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ABSTRACT

This publication describes 33 research projects supported by the federal Maternal and Child Health Bureau and completed in 1989, 1990, and 1991. It is the third edition in a series of collected abstracts of completed maternal and child health research projects. Each project abstract contains the name of the grantee, name and address of the investigator, project costs, statement of the problem, research questions addressed, study design and methods, study sample or population, findings, recommendations, and publications. The research projects focus on the following topics: school-age very low birthweight children, infant health and development, health and nutritional status of Mexican-American children, pesticide exposure and pregnancy outcome, chronically ill children's use of time out of school, mothers and deaf infants, intravenous antibiotic therapy in cystic fibrosis, trace metal interactions in lead-exposed children, closed head trauma in adolescence, child care arrangements and acute illnesses in preschoolers, financing maternity care, early intervention, infants of depressed adolescent mothers, technology-dependent children, coping with sudden infant death syndrome, paternal unemployment, grandfather influence, memory, standards for the evaluation of growth and nutritional status, follow-up care for premature infants, neonatal outcome and weight gain of Black adolescents, biotinidase deficiency in newborns, infant abuse and neglect, auditory testing, early intervention in failure to thrive, otitis media, uterine contractions in Black women, perinatal regionalization, breastfeeding, sickle cell anemia, listening partners, mothering in adolescence, and epilepsy in pregnancy. In addition to the abstracts, the publication contains an analytic section on products and highlights resulting from the research projects completed in 1987 through 1991 and a section listing all of the final reports of research projects received by the Maternal and Child Health Bureau from 1980 through 1991. (JDD)

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CHILD HEALTH

RESEARCH PROGRAM

Completed Projects 1989, 1990, and 1991



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CHILD HEALTH

RESEARCH PROGRAM

Completed Projects 1989, 1990, and 1991

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TABLE OF CONTENTS

Prefa	ace	. v
MCF	HB Completed Research Projects 1987–1991: Products and Projects Highlights	vii
Com	pleted Projects Abstracts 1989, 1990, 1991	1
	Developmental Dysfunction in School Age Very Low Birthweight Children	3
	The Infant Health and Development Program	6
	Health and Nutritional Status of Mexican-American Children	. 14
	Pesticide Exposure and Pregnancy Outcome	. 22
	A Survey of Chronically III Children's Use of Time Out of School	. 28
	Interaction and Support: Mothers and Deaf Infants	. 35
	Intravenous Antibiotic Therapy in Cystic Fibrosis: Home Versus Hospital	. 44
	Trace Metal Interactions in Lead-Exposed Chiluren	. 49
	Course of Recovery for Closed Head Trauma in Adolescence	. 56
	Child Care Arrangements and Acute Illnesses in Preschoolers	. 60
	Impacts of Financing Maternity Care for the Poor and Uninsured	. 63
	The Early Intervention Collaborative Study: Phase One	. 67
	Infants of Depressed Adolescent Mothers	. 82
	State Census of Technology-Dependent Children	. 86
	SIDS Loss: Psychosocial Impact and Predictors of Coping	91
	Consequences for Children of Paternal Unemployment Lewis H. Margolis, M.D., M.P.H., University of Michigan	99
	Grandfather Influence on Young Children of Teenage Mothers	103



Improving Memory of EMR Children
Anthropomorphic Standards for the Evaluation of Growth and Nutritional Status 115 Roberto A. Frisancho, Ph.D., University of Michigan
Cost of Followup Care for Prematures
Neonatal Outcome and Weight Gain of Black Adolescents
Pilot Screening for Biotinidase Deficiency in Newborns
Stress, Social Support, and Abuse and Neglect in High-Risk Infants
Improving Auditory Testing of Multihandicapped Children
Prediction of Outcome of Early Intervention in Failure to Thrive
Adenoidectomy, Eustachian Tube Function and Otitis Media
Cohort Study of Uterine Contractions in Black Women
Diagnosis Related Groups (DRGs) and Their Impact on Perinatal Regionalization 153 Rachel M. Schwartz, M.P.H., Women and Infants' Hospital of Rhode Island
Acculturation, Psychosocial Predictors, and Breastfeeding
Sickle Cell Anemia: DNA for Newborn Screening Followup
Listening Partners: Psychosocial Competence and Prevention
Mothering in Adolescence: Factors Related to Infant Security
Epilepsy in Pregnancy: Developmental Followup of Infants
Appendixes
Completed Projects Publications 1987–1991
Final Reports In NTIS
Indexes
Grantee Index
Project Index



6

PREFACE

Safeguarding and improving the health of mothers and children is a demanding national responsibility. It requires a significant expenditure of funds and a critical mass of highly trained and dedicated professionals. It entails systems of vital statistics, and laboratory and hospital reporting to monitor morbidity and mortality events as they happen and where they happen. Also needed are private and state-supported professional schools to train new practitioners and update seasoned clinicians in the latest advances in the health sciences. Above all, safeguarding and improving the health of mothers and children requires an expanding scientific knowledge base and the means for scientists and practitioners to draw upon such a base with accuracy and speed.

Research is the mechanism through which our scientific knowledge base expands. Expansion comes about through the generation of new knowledge and through the validation or rejection of existing scientific facts. These knowledge-expanding activities do not materialize overnight, and at the research project level, they do not often produce more than incremental gains in knowledge. For the most part, individual research projects are carefully thought out investigations that take several years to complete. Modest contributions to the knowledge base are, therefore, the rule rather than the exception.

Quality research requires more than the application of the scientific method to the collection of data and the careful monitoring of the research in the laboratory or in field situations. With few exceptions, it is essential that the research proposal be peer reviewed and assessed for originality, importance, and technical quality at the planning stage. Only if the proposed research can pass this scrutiny should it be allowed to proceed and result in a significant expenditure of national resources. At completion, research needs to be peer reviewed again before its findings can be published in professional journals, a prerequisite for acceptance by the scientific community.

After acceptance by the scientific community and incorporation into the knowledge base, research findings need to be pushed forward to the application stage. As with formulating and executing research, translating research findings into clinical application calls for careful planning, imaginative thinking, and hard work. For several reasons, publication of findings in scientific journals does not automatically proceed to clinical application. Sometimes professional inertia is the culprit. At other times, the potential for clinical application may not be fully realized. Not infrequently, an additional piece of knowledge is needed to complete the puzzle that will make a body of findings applicable to clinical situations. In rare instances, the findings are so discordant with the existing knowledge base that they elicit resistance to their adoption from those likely to profit from them the most. Often, research findings are not applied in health care delivery situations simply because they are not known to the prospective users, a problem that this publication—and the series of which it is a part—is intended to address.

This publication, a companion volume to the recently published *Maternal and Child Health Research Program: Active Projects FY 1990 and FY 1991*, informs maternal and child health practitioners and scientists of the availability of findings from 33 research projects supported by the Maternal and Child Health Bureau and completed in 1989, 1990, and 1991. It is the third edition in a series of collected abstracts of completed maternal and child health research projects. These abstracts are based on the final reports submitted by investigators to the Maternal and Child Health Research Program Office. Because this book is third in a series, it contains a cumulative list of publications arising out of the research projects completed in 1987 and 1988, as well as those completed in 1989, 1990, and 1991. Project



investigators whose work was completed in 1987 and 1988 were asked in 1992 to compile an updated list of products relating to their grant. This inquiry will be repeated for the 1992 and 1993 completed projects publication. Thus, the list of publications appearing in future issues of this book should grow considerably and be a valuable source of information for practitioners, administrators, and researchers working to improve the delivery of services to mothers and children.

This publication also contains (1) an analytic section on what was produced by the research projects completed in 1987 through 1991, and (2) a section listing all of the final reports of research projects received by the Maternal and Child Health Bureau from 1980 through 1991. As the analytic paper attests, the publication record for the 1987 through 1991 cohort of completed projects was outstanding—an average of 3.7 peer-reviewed articles per completed project. The majority of the published articles appeared in the Nation's most prestigious medical and scientific journals.

The projects' final reports have been entered into the National Technical Information Service (NTIS), from which they can be purchased. Information on price and on how to order the final reports from NTIS is included in the last section of this book. In addition to presenting substantive findings in great detail, the final reports include technical information on how the investigators approached their research projects. This should be instructive for new as well as experienced investigators. Frequently, the final reports include extensive critical reviews of the pertinent literature and reports of "no findings." Reports of "no findings" are seldom published in peer-reviewed journals, yet they can be as important for the advancement of knowledge as published findings.

Gontran Lamberty, Dr.P.H. Director, Maternal and Child Health Research Program October 1, 1993



MATERNIAL AND CHILD HEALTH BUREAU COMPLETED RESEARCH PROJECTS, 1987–1991: PRODUCTS AND PROJECT HIGHLIGHTS

Introduction

Many approaches can be taken to assess the performance of health and medical care research at the project or program level. One approach is to compare the cost of doing the research with the benefits produced, as measured by such indicators as the number of lives saved, the number of years of life added, the amount and kinds of disabilities prevented, the resulting quality of life, and the health care dollars saved. A second approach is to determine the clinical importance of the findings that were produced and their direct and indirect contributions to the scientific knowledge base. The latter analysis can be made by expert panels or by determining the number of scientific prizes won, spinoff investigations generated, articles and books published, formal citations received in refereed journals, etc. One chooses a method based on one's goals for the assessment as well as the amount and kinds of resources available. By analyzing the products of MCHB-funded research projects, and describing the clinical and scientific contributions of selected projects, this publication provides valuable information for assessing the performance of the MCHB Research Program.

As part of its routine program monitoring activities, the Maternal and Child Health (MCH) Research Program asks principal investigators (Pis) to report, for each research project completed, the number and types of products generated (e.g., presentations at professional meetings, articles published in peer-reviewed journals, books or chapters in books, published abstracts, doctoral dissertations). The first reporting takes place as part of the submission of a final report, one of the requirements for receiving Federal research grant awards. Since it takes 1 to 5 years to fully analyze the data collected in an investigation, a sperial followup query takes place annually for a period of 5 years following completion of the study to capture any additional products. For peer-reviewed articles, the PIs are also asked to name the journals in which their articles were published and to list the publication date. A sample of the reported publications are located to verify that they actually have been published; they are then read to determine if their content corresponds to the research questions on record for the project that produced them. While imperfect, indicators such as the number and types of products generated and the types of journals where the research findings are published provide valuable clues to the quantity and quality of the products the MCH Research Program as a whole generates.

Number and Types of Products Generated

The 66 research projects completed in 1987 through 1991 reported 1,006 products, or an average of 15.2 products per project (Table 1). Slightly over 50 percent (508) of the products consisted of presentations at professional meetings, conferences, and workshops; 24.6 percent (247) represented articles published in journals (the vast majority peer reviewed); 8.8 percent (89) consisted of books and chapters in books. Five doctoral dissertations were reported, a figure well below expectations. One suspects considerable underreporting, perhaps a result of how the information is currently gathered. Based on the number and types of products generated, it appears that



Table 1. Type and Number of Products Generated by MCHB-Supported Research Based on Final Reports and Followup Queries: 1987-91

Type of Products	1987	1988	1989	1990	1991	Total
Presentations	54	51	110	169	124	508
Peer-Reviewed Published Articles	79	44	53	33	38	247
Chapters in Books	18	. 7	22	14	22	83
Books	2	1	0	0	3	6
Abstracts	15	20	27	17	4	83
Dissertations	0	0	.4	0	1	5
Manuscripts in Preparation/ Submitted	4	1	7	50	12	74
Total Products	172	124	223	283	204	1,006
No. of Projects	20	13	13	10	10	66
Average No. of Products Per Project	8.6	9.5	17.1	28.3	20.4	15.2
Average Number of Peer-Reviewed Published Articles per Project	3.9	3.4	4.1	3.3	3.8	3.7

information about the projects supported by the MCH Research Program is being disseminated quite well.

There is an average of 3.7 peer-reviewed articles per project. Considering the quality of the peer-reviewed journals in which the research findings are published, this publication rate suggests that the MCH Research Program is one of high scientific quality and productivity. This, in turn, suggests that the stringent review standards the program has been using over the past decade are paying good dividends (see the "Program Activities" section on page ix of the companion publication *Maternal and Child Health Research Program: Active Projects FY 1990 and FY 1991* for an explanation of the review process).

Where Research Findings Were Published

Table 2 presents information about the types of journals in which the findings of the 66 completed research projects were published. As Table 2 indicates, approximately 46 percent (114) of the 247 articles produced were published in medical journals. Nearly three-fourths of these 114 publications appeared in pediatric journals, with the rest published in general medicine and obstetrical journals. These figures align well with information regarding who applies to the MCH Research Program and what research questions are being addressed by funded projects. They match well also with the pediatric focus of the service programs that the Maternal and Child Health Bureau (MCHB) supports and the list of priorities promulgated for the MCH Research Program.

A significant number (about 22 percent) of all the reported peer-reviewed articles were published in behavioral sciences journals. Table 2 also shows smaller but significant representation among journals in epidemiology and public health, nursing, and allied health professions. These figures understate the representation of these disciplinary



Table 2. Number and Percent Distribution of Articles Generated by MCHB-Supported Research According to Type of Journal Where Published: 1987-91

Type of Journal	Number of Articles	Percent
Total	247	100.0
Medical—General	20	8.1
Medical—Pediatrics	8-1	34.0
Medical—Obstetrics	10	4.0
Behavioral—General	30	12.1
Behavioral—Pediatrics	24	9.7
Epidemiology and Public Health	14	5.7
Nursing	5	2.0
Allied Health Professions	18	7.3
Basic, Laboratory, and Clinical Sciences	30	12.1
Other	12	4.9

approaches in the research being supported by MCHB. Publication of health-related research in clinical medicine journals rather than in disciplinary (e.g., economics, psychology) journals has been an evolving trend that reached new heights in the 1980s. Thus it is not surprising nowadays to see in *The New England Journal of Medicine*, the *Journal of the American Medical Association (JAMA)*, or *Pediatric* research articles of note that in years past would have been published as lead articles in disciplinary journals such as *Child Development*, *Medical Care*, the *American Journal of Epidemiology*, or the *American Journal of Public Health*. The prestige of some of the medical journals is a factor fueling this trend. So is the scientific rigor of the review process of these journals, which makes acceptance for publication an important professional accomplishment. Publication in these journals in turn supports academic promotion. Another contributing factor is the wide and influential audiences these journals reach, which gives findings a greater dissemination potential and a correspondingly greater chance for translation into service application and policy decisions.

Slightly more than 1 in 10 (12.1 percent) of the 247 articles were published in basic, laboratory, and clinical science journals. A number this high might seem surprising, given the applied nature of the MCH Research Program. However, what the figure indicates is the well-known but seldom-acknowledged fact that there is a two-way flow in contributions between basic and applied research. Most of the basic/clinical science articles came from research projects seeking to apply knowledge in the basic sciences to create and/or evaluate new laboratory tests and screening instruments. Two cases in point are the evaluation, under a randomized clinical trial, of the efficacy of three commercial kits for detecting sexually transmitted diseases in women, and the application of new knowledge in molecular biology to improve the reliability of laboratory procedures for detecting fragile X syndrome prenatally. Both of these investigations were



judged to be applied research and not eligible for consideration by Federal agencies supporting basic research. This underscores the often overlooked benefits of multiple Federal research programs.

Table 3 presents in more detail the information contained in Table 2. Specifically, they provide a list of specific journals for each category, along with the number of articles published in each journal. As may be seen, most articles that appeared in medical publications did so in the most rigorous and prestigious journals, including *The New England Journal of Medicine, The Journal of the American Medical Association, Obstetrics and Gynecology,* and *Pediatrics.* Among the pediatric journals, over one-half of the 84 articles appeared in *Pediatric Research,* the *Journal of Pediatrics, Pediatrics,* and the *American Journal of Diseases of Children.* The articles published in behavioral science journals follow the same trend, although in this category there is less concentration in specific journals. For the most part, the journals in which behavioral sciences articles were published reflected the multidisciplinary clinical approaches to care emphasized by MCHB.

Past Examples of Outstanding Investigations

Among MCHB-supported studies that made important contributions to the prevention and amelioration of disease and disabilities in children during the 1970s were: (1) Jekel and Klerman's research on programs for unwed teenage mothers; (2) Furstenberg's research on the social consequences of teenage childbearing; (3) Werner's longitudinal research on the children of Kauai; (4) Haverkamp's research on fetal heart rate monitoring and scalp sampling in high-risk pregnancies; and (5) Chess' studies on children who were exposed in utero to rubella.

The studies on teenage mothers by Jekel, Klerman, and Furstenberg are models of their kind. Their importance lies not so much in how well they documented the social, psychological, and economic consequences of unplanned parenthood for teenagers, but how influential their findings have been in bringing the problem to national attention and in shaping the content of prevention-oriented programs.

Werner's Kauai studies are classic longitudinal child growth and development research. They underscored key factors in the prenatal, natal, and postnatal environments that may have a cumulative, long-term effect upon the development of children. Findings from the studies have been used extensively to support the need for a national system of preschool health programs and periodic early childhood screening. Of great importance was the demonstration that the social context, in addition to perinatal factors, determines later outcomes along a variety of domains. These results have influenced the deployment of public health resources, as well as identifying high-risk factors signaling the need for followup and early intervention efforts.

The two pioneer studies by Haverkamp on fetal heart rate monitoring were instrumental in focusing national attention on the need to evaluate medical technologies before they are widely used in medical practice.

Chess' longitudinal research on children whose mothers experienced a rubella infection during pregnancy poignantly documented the disastrous effects of in-utero viral infections on the developing fetus, and were also instrumental in developing new



12

Table 3. Articles Published From MCHB-Funded Research, 1987-91

Туре	Title	Number of Articles	Туре	Title	Number of Articles
<u>- 7 P c</u> Medical	AIUC	VI IM HICKS	Behavior		
· · · · · · · · · · · · · · · · · · ·	Now England Iournal of		GENERAL	Social Science and Medicine	5
GENERAL	New England Journal of Medicine	o	GENERAL.	American Journal of Mental	,
		8		Retardation	4
	Critical Care Medicine	3		American Journal of	4
	Journal of the American	, ,		Orthopsychiatry	2
	Medical Association (JAMA)	3		Journal of Consulting and	2
	American Journal of	1		Clinical Psychology	2
	Preventive Medicine Clinical Research	1		Journal of Family Violence	2
		1		Annual Review of Psychology	
	Journal of Family Practice	1		Applied Psychological	1
	Lancet	1		Measurement	1
	Patient Care	$\frac{1}{20}$			1
	TOTAL	20		Culture, Medicine and	1
PEDIATRICS	Pediatric Research	18		Psychiatry	
	Journal of Pediatrics	15		Education and Training of the	
	Pediatrics	11		Mentally Retarded	1
	American Journal of Diseases			Educational Psychology	1
	of Children	7		Measures	1
	Developmental Medicine and			Family Relations	1
	Child Neurology	6		Journal of Personality and	_
	Journal of Adolescent Health			Social Psychology	1
	Care	6		Journal of Smith College	
	Journal of Behavioral and			School of Social Work	1
	Developmental Pediatrics	6		Journal of Social Issues	1
	Pediatric Pulmonary			Journal of Social Service	
	Supplement	4		Research	1
	Clinical Pediatrics	2		Merrill-Palmer Quarterly	1
	Insights into Pediatrics	2		Patient Education and	
	Pediatrics in Review	2		Counseling	ì
	Advances in Neonatal	-		Psychiatric Annals	1
	Screening	1		Psychology and Health	1
	Child and Adolescent	1		Social Cognition	_1
	Psychiatry	1		TOTAL	30
	Current Opinions in Pediatric	=	PEDIATRICS	Journal of Early Intervention	4
	Exceptional Children	î		Child Abuse and Neglect	3
	Pediatric Clinics of North	•		Journal of Adolescent	.,
	America	1		Research	2
	TOTAL	84		Journal of Pediatric	-
				Psychology	2
OBSTETRICS	Obstetrics and Gynecology	3		Child Care, Health and	-
	American Journal of			Development	1
	Obstetrics and Gynecology			Developmental Psychology	1
	Prenatal Diagnosis	2		Early Child Development and	-
	American Journal of			Care	. 1
	Perinatology	1			1
	Clinical Obstetrics and			Early Development and	1
	Gynecology	1		Parenting	1
	Seminars in Perinatology	_1		Early Education and	•
	TOTAL	10		Development	1

continued on next page



Table 3. Articles Published From MCHB-Funded Research, 1987-91 (continued)

Туре	Title	Number of Articles	Туре	Title	Number of Article
Behavior	al (cont'd.)		Allied He		
PEDIATRICS	Journal of Applied		Professi	ons	
(cont.d.)	Developmental Psychology	1		Journal of the American	
	Journal of Clinical Child			Dietetic Association	5
	Psychology	1		American Journals of the Deal	f 3
	Journal of Youth and			American Journal of Clinical	
	Adolescence	1		Nutrition	3
	New Directions for Child	·		Ear and Hearing	2
	Development	1		British Journal of Audiology	i
	Social Policy Report of SRCD	1		Journal of Human Lactation	1
	SRCD Monographs	i		Journal of Speech and	
	Topics in Early Childhood	•		Hearing Research	1
	Special Education	1		Nutrition Research	1
	Zero to Three			Volta Review	1
		$\frac{1}{24}$		TOTAL	18
	TOTAL.	24	Basic, La		
Epidemio	ology		and Clin	ical Sciences	
-	ic Health			Yale Journal of Biology and	
	American Income at a C Destate			Medicine	3
	American Journal of Public	,		American Journal of Human	
	Health	3		Biology	2
	American Journal of			American Journal of Human	
	Epidemiology	2		Genetics	2
	American Journal of Health			American Journal of Physical	
	Promotion	!		Anthropology	2
	Children and Youth Services			Biochemical Medicine and	
	Review	1		Metabolic Biology	2
	Family and Community			Human Biology	2
	Health	1		Journal of Chromatography	2
	Genetic Epidemiology	1		Journal of Clinical	
	International Journal of		•	Microbiology	2
	Mental Health	1		Anals of the New York	
	Journal of Community Health	1 1		Academy of Sciences	1
	Journal of Public Health			Clinical Chemistry	1
	Dentistry	1		Clinical Pharmacology and	
	Journal of School Health	1		Therapeutics	1
	Public Health Reports	.1		Developmental Pharmacology	<i>;</i>
	TOTAL	14		and Therapeutics	1
				Enzyme	l
Nursing		•		Epilepsia	1
	Journal of Pediatric Nursing	2		Goldfranks Toxicologic	
	American Journal of Materna			Emergencies	1
	and Child Health Nursing	1		Journal of Pharmacology and	
	Journal of Child and	1		Experimental Therapeutics	1
	•			Medical Toxicology	ŀ
	Adolescent Psychiatric and	1		Neurotoxicology	
	Mental Health Nursing	1		PCR Methods and Application	s l
	Nursing Research	<u></u>		Teratology	I
	ТОГАІ.	5		Yearbook of Physical	1
				Anthropology	1 20
				TOTAL	30



approaches to the care of the multihandicapped child. The biobehavioral concept of "temperament" as a mediator of children's adaptation to multiple handicaps came out of Chess' studies.

Examples of studies that made significant contributions during the first half of the 1980s were: (1) Klaus and Kennel's studies on maternal-infant attachment; (2) Main and Creasy's evaluation of technologies and clinical management approaches used to prevent preterm delivery in high-risk pregnancies; and (3) Olds' study of the effects of a nurse home visitation program on pregnancy outcome, child growth and development, and the reduction of child abuse.

Klaus and Kennel's studies on maternal-infant attachment, conducted in the environment of neonatal intensive care units (NICUs), revolutionized the care and treatment of critically ill neonates worldwide and were instrumental in initiating a new line of research on the significance of human touch and handling for the physical growth and cognitive development of infants. The new handling approaches developed by the studies were instrumental in reducing the number of days the critically ill neonates remained in the expensive environment of the NICU by an average of 4 days. This translated into millions of dollars saved and in sizeable reductions in NICU-acquired infections.

The studies by Main and Creasy evaluated, under randomized childred trial conditions, new obstetrical technologies for monitoring uterine activity. These new technologies hold promise for preventing preterm labor and currently provide critical insights into the basic processes of uterine musculature contraction and the initiation of premature labor.

Olds' classic study (the Elmira Study) of the effects of a nurse home visitation program on pregnancy outcome, child growth and development, use of preventive health services (e.g., childhood immunizations), and the prevention of child abuse and unintentional injuries in children documented the benefits of an old public health approach long out of use. This successful randomized clinical trial of a comprehensive approach to the prevention of multiple maternal and child health problems proved to be highly cost effective and was instrumental in the revival of home visiting programs in other areas of health and social welfare. A replication of the study is currently being done in Memphis/Shelby County, Tennessee, under the joint support of the Maternal and Child Health Bureau and the National Center for Nursing Research, National Institutes of Health. This replication is an attempt to test the generalizability of the approach by shifting the site of service from one that was rural and sparsely populated to one that is urban/metropolitan and densely populated. Nurses currently being used in the replication study are county health department nurses without graduate degrees and with larger patient loads. The nurse visitation study by Olds was instrumental in creating Federal legislation making possible the use of this approach on a larger scale with local community participation and direction.



Current Examples of Outstanding Investigations

Three projects of note were completed between 1989 and 1991: (1) The Infant Health and Development Program; (2) the Early Intervention Collaborative Study-Phase 1; and (3) Anthropomorphic Standards for the Evaluation of Growth and Nutritional Status.

The Infant Health and Development Program (IHDP) was a multisite, randomized clinical trial which sought to test the effectiveness of combined quality pediatric health care and early intervention services on the prevention of health and developmental problems in low birthweight infants. The study was jointly supported by the Maternal and Child Health Bureau, the National Institute on Child Health and Human Development, and The Robert Wood Johnson Foundation. Study findings showed significant effects on an array of health and child development outcomes, including impressive gains in cognitive abilities. The effects of the combined intervention were greatest on minority low birthweight infants (i.e., African Americans and Hispanics) and in growth and development areas where premature infants and minority children traditionally do poorly. An expanded version of the study (Project Begin) is currently being established, with support from the Centers for Disease Control and The Robert Wood Johnson Foundation. Followup studies of the infants who participated in IHDP are currently in progress under the joint support of the Maternal and Child Health Bureau and the National Institute on Child Health and Human Development. Preliminary findings indicate enduring gains at the point of entering school age.

The Early Intervention Collaborative Study by Shonkoff sought to evaluate the effects of various intervention programs operating in several New England States on young children with developmental vulnerabilities and their families. Study findings documented a mix of negative and positive findings, all emphasizing the complexities involved in delivering services to an extremely vulnerable group of children. A followup study currently in progress under the support of MCHB addresses both theoretical and pragmatic concerns facing the field of early intervention for young children with developmental vulnerabilities and their families. The ongoing study builds on findings that emerged during the earlier study and is designed to explore the stability and durability of subgroup differences related to both vulnerability and resilience over the entire early childhood period. The study findings promise to provide vital information to assist policymakers and service providers in determining the most equitable and beneficial distribution of limited program resources.

The study by Frisancho on anthropometric standards for the evaluation of growth and nutritional status satisfied a clinical need of long standing—being able to distinguish the truly malnourished from the simply underweight, and the obese from the normally heavy. Using data already collected by two National Health and Nutrition Examination Surveys (HANES I and HANES II). Frisancho developed means, standard deviations, and percentiles, by age, gender, and frame size, of anthropometric dimensions of body size and body composition. These measures of central tendency and dispersion can be used in evaluating growth and nutritional status of children and adults. Included in the products of the investigation were illustrations and practical examples of the use of anthropometric dimensions in diagnosing the nutritional status of clinical and nonclinical populations.



xiv

Summary and Conclusions

The performance of 66 research projects completed in 1987 through 1991 under the support of the MCH Research Program has been assessed and past and recent examples of outstanding investigations have been described. Based on the number and types of products generated by the 66 projects, it can be concluded that research findings of projects supported by the Maternal and Child Health Bureau are being disseminated quite well, using the time-proven methods employed by the scientific community at large, and through prestigious and influential outlets. The latter is of note as it suggests that findings of MCHB-supported research have a greater than average chance of being translated into clinical applications and policy decisions.



COMPLETED

PROJECTS

ABSTRACTS

1989, 1990, AND 1991



DEVELOPMENTAL DYSFUNCTION IN SCHOOL AGE VERY LOW BIRTHWEIGHT CHILDREN

GRANTEE University of Alabama at Birmingham

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PROJECT NUMBER MCJ-015310

REPORT NUMBER MCH/CCS-90/01

NTIS NUMBER PB92-135565

Project Period 03/01/86-02/28/89

Costs* Year 1 Year 2 Year 3 Year 4 Year 5
Awarded † † † n/a n/a
Requested † † † n/a n/a

SUMMARY

Statement of the Problem

Survival has improved dramatically for children with birthweights less than or equal to 1,000 grams. Questions remain about the quality of life for survivors. Major morbidity appears to be decreasing and most very low birthweight infants survive infancy apparently intact. As more of these children reach school age, there are indications that the "normal" population of survivors experience unanticipated behavioral and scholastic difficulties. This project examined the extent of these dysfunctions and the issue of whether the behavioral and learning problems could have been predicted from preschool and infant evaluations.

Research Questions or Hypotheses

This study was designed to test the following hypotheses in a very low birthweight population without physical handicaps and mental retardation:

- 1. Very low birthweight children are at higher risk for poor academic performance than children with normal birthweights.
- 2. Neurodevelopmental assessments and psychological tests performed in early childhood may predict later academic achievement.



^{*} Indirect included/† Not available at the time of publication.

- 3. Developmental outcome of very low birthweight children can be related to specific prenatal or perinatal events.
- 4. Very low birthweight children will exhibit some specific areas of weakness in achievement in academic subjects and psychological functions when compared with full-term, demographically similar children.

Study Design and Methods

A case-control study was performed comparing school-age children of very low birthweight with demographically similar children without very low birthweight. Both groups were tested on the following factors:

- 1. Sociocultural factors, using the Social Readjustment Rating Scale, the Coddington Life Events Scale, and the Parenting Stress Index;
- 2. Academic performance, using school questionnaires and the Wide Range Achievement Test (WRAT);
- 3. Cognitive function, using the Wechsler Intelligence Scale for Children-Revised (WISC-R);
- 4. Behavioral factors, using the Quay and Peterson's Revised Behavior Problem Checklist, and the Piers-Harris Children's Self Concept Scale;
- 5. Motor performance, using the Bruininks-Oseretsky Test, the Southern California Motor Accuracy Test, the Grooved Pegboard Test, the Motor Impersistence Test, the Bender Gestalt Test, and the Test of Visual Analysis Skills;
- 6. Sensory perception/memory, using the Tactual Performance Test and the Fingertips Number Writing Test;
- 7. Language, using the Clinical Evaluation of Language Function (CELF); and
- 8. Abstract thinking, using the Categories Test.

All subjects were also given a physical examination. In addition, since the very low birthweight children had been seen for previous developmental testing at 1 and 4 years of age, analysis of the predictive ability of these prior assessments for school-age performance was conducted.

Study Sample and/or Population

The study population comprised 77 very low birthweight children ages 6–11, who had no evidence of major handicaps (IQ less than 70, cerebral palsy, or sensory impairment) at their last visit to our comprehensive followup program; the last visit must have occurred after the child's first birthday. The comparison population was recruited from school children who were matched for age, race, gender, and household income, and who had birthweights greater than 2,500 grams.

Findings

In all categories tested, the very low birthweight children scored lower than did the controls (whose birthweight exceed 2,500 grams). Subjects who had very low birthweight were significantly shorter and weighed less, though body fat was similar. Intelligence testing with the WISC-R revealed results averaging 10 points lower for the study population. Similarly, achievement scores, visual perception, and language and motor



scores were significantly lower for very low birthweight children. There was no overall difference in family stress or life events. Very low birthweight children required or were receiving special education services more frequently than their peers. Finally, self-concept was significantly lower for the very low birthweight subjects and they were described by their teachers as less popular with classmates than those in the control group. Maternal education was associated with performance, with those very low birthweight children whose mothers were not high school graduates scoring 20 points less than children in the control group whose mothers had at least a high school education. Other medical or social variables did not predict outcome in the models tested. The Stanford-Binet Intelligence Scale at age 4 also was significantly associated with subsequent test results, although the Bayley Scales of Infant Development and early neurodevelopmental test results were not able to predict outcome at 6–11 years of age.

Recommendations

Since very low birthweight survivors appear to be at significant risk for poor academic performance, early identification of these children within educational systems should allow opportunities for enrollment in programs designed to encourage achievement. The most effective type of intervention is not clear.

Future research should examine (1) the effective use of followup programs (i.e., who is most likely to benefit from longitudinal services?); (2) the functional status and behavioral and mental health outcomes of the children, and perceptions of health by parents and health professionals; (3) the social ecology of very low birthweight families; and (4) the evaluation of interventions that may affect outcome for very low birthweight children.

PUBLICATIONS

Articles and Chapters

None to date.

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THE INFANT HEALTH AND DEVELOPMENT PROGRAM

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 Costs*
 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 Awarded
 524,512
 496,600
 586,546
 571,980
 n/a

 Requested
 630,937
 633,439
 705,450
 657,177
 n/a

SUMMARY

Statement of the Problem

Low birthweight premature infants are at increased risk in early life for a variety of medical complications and later for developmental delay, behavior problems, learning problems, and difficulties in school performance. Moreover, socioeconomic disadvantage—itself, a risk factor for low birthweight and prematurity—also increases the likelihood of adverse developmental outcomes and scholastic problems.

The extent to which neonatal or later interventions can prevent or ameliorate adverse outcomes in this vulnerable population is uncertain because even the best-designed interventions for these infants have involved single sites with small numbers. The most persuasive evidence that early intervention might avert negative childhood outcomes is found in studies of primarily normal birthweight infants and preschoolers from socially disadvantaged families. The applicability of such programs to low birthweight premature infants required empirical investigation.

Research Questions or Hypotheses

The present study is the first multisite, randomized clinical trial designed to evaluate the efficacy of combining early child development and family support services with



[•] Indirect included/jointly funded with the National Institute for Child Health and Human Development and the Robert Wood Johnson Foundation.

pediatric followup in reducing the developmental, behavioral, and health problems among low birthweight premature infants (here defined as having a birthweight less than or equal to 2,500 grams and a gestational age less than or equal to 37 weeks). The main research questions addressed issues of whether, at 36 months of age, children who were receiving the intervention differed from children who were not receiving the intervention in (1) cognitive development, (2) behavioral competence, or (3) health status.

Study Design and Methods

Infants were andomly assigned either to an intervention group or to a followup group. The intervention group received a home visitation program, a center-based child development program, and parent group meetings plus high quality pediatric followup. The followup group received only the pediatric followup, which consisted of assessments at regular intervals from 40 weeks to 36 months plus referrals for pediatric care and other services as indicated. All ages were corrected for prematurity. Eight medical institutions serving diverse demographic populations in different geographic locations participated in the clinical trial.

The services exclusively for the intervention group consisted of the following:

- 1. Home visits: The professional educators who visited the homes once a week in the first year and then every 2 weeks for the next 2 years brought special toys and taught the mothers activities to use to develop the babies' skills. They also helped the mothers to deal with problems in caring for low birthweight infants as well as their own life problems.
- 2. Child development centers: The centers, developed at each site exclusively for the children in the intervention group, offered a safe high quality environment and continued the same educational program used for the home visits. Recommended attendance was 5 days per week, beginning at 12 months and continuing until 36 months.
- 3. Parent groups: Bimonthly parent group meetings provided information on child rearing, health and safety, and other parenting concerns.

Eight primary outcome measures were chosen to address the three main research questions. For cognitive development, the Stanford-Binet Intelligence Scale, Form LM, third edition, was administered at 36 months. For behavioral competence, the Child Behavior Checklist was used for children ages 2–3 years. Health status was regarded as multidimensional. Since no single comprehensive measure existed, six different measures were selected to assess morbidity, functional status, and maternal perception of the child's health.

A variety of other data were collected in the areas of maternal mental and physical health and social functioning; familial and home environment characteristics; use of health and social services; and other infant behavioral, health, and neurodevelopmental characteristics. Conceptually, the program design recognized that a number of secondary outcomes were related to participation in the program. These involved variables such as



(1) changes in maternal employment and education, (2) use of health and social services,

(3) quality of the home environment, (4) mother-child interaction patterns, and (5) maternal problem-solving skills. Other data being used for additional studies include descriptions of the natural history of low birthweight premature infants, prediction studies, model building studies, and methodological studies.

Study Sample and/or Population

Eight medical institutions that serve diverse demographic populations in different geographic locations were selected through a national competitive review. A total of 4,551 newborn infants who would reach 40 weeks' postconceptional age between January 7, 1985 and October 9, 1985, and whose birthweights were 2,500 grams or less were screened at birth for eligibility. Of these, 3,249 infants were excluded before randomization by protocol criteria related primarily to (1) residence; (2) gestational age greater than 37 weeks, as assessed by a modification of the Ballard Examination; or (3) hospital discharge before or after the designated recruitment period. Unhealthy infants were included unless they had an illness or neurological deficit so severe as to preclude participation in the intervention program; only 61 such infants were excluded. Thus, the sample included the majority of low birthweight premature infants who survived the neonatal hospitalization and lived in the catchment area (i.e., within 45 minutes of each center). Of the 1,302 who met the eligibility criteria, the parents of 274 (21 percent) refused consent to be randomized. Of the 1,028 infants who had parental consent and were randomized, 43 were withdrawn before participating in the study. The remaining 985 infants constituted the primary analysis group on which the findings of this report are based.

The research design included stratification by eight sites and two birthweight groups. Infants who weighed between 2,001 and 2,500 grams were designated heavier; those who weighed 2,000 grams or less were designated lighter. One-third of the sample came from the heavier group and two-thirds from the lighter group. To minimize the cost of the study, subjects within each weight group were allocated in such a way that one-third were randomized to the intervention group and two-thirds to the followup group. The targeted overall sample size was based on an estimated effect size (ES = difference between treatment group means, expressed in standard deviations) of 0.5. For a single outcome, a power of 99 percent (p=.05, two-tailed) was required in the total group and in the lighter group alone.

Based on our research design, the target number of patients at each of the eight sites was 135. Although this goal was not reached at all sites, the actual enrollment remained adequate for a power of at least 99 percent.

Immediately after hospital discharge, patients were randomized by the National Study Office using an adaptive method that monitored for a 2:1 balance and for absence of bias between the two study groups in each site and birthweight stratum. In the randomization, balance was monitored for birthweight, gender, maternal education (less than high school graduate, high school graduate, some college, or more), maternal race (black, Hispanic, and white/other), primary language in the home, and infant participation in another study.



Findings

Of the 985 children in the primary analysis group, 913 participated in at least one aspect of the final 36-month assessment (93 percent of the intervention group and 93 percent of the followup group).

Overall, the mean IQ scores on the Stanford-Binet Intelligence Scale were significantly higher for the intervention children than for the followup children. Scores were 13.2 IQ points higher (ES = 0.83, p<.001) in the intervention group with birthweights ranging from 2,001 grams to 2,500 grams, and 6.6 IQ points higher (ES = 0.41, p<.001) in the intervention group with birthweights of 2,000 grams or less. The only initial status variable that influenced the overall effect was birthweight; the difference in IQ scores between the intervention and followup groups increased as birthweight increased (p=.01).

Although the difference in behavioral competence between treatment groups was small, the number of behavior problems reported by mothers of the intervention group was significantly less than the followup group (ES=-0.18, p=.006). Maternal education was the only initial status variable that influenced the effect of the treatment. Among children of high school graduates, there was little difference between the two groups, whereas among children whose mothers did not graduate from high school, those in the followup group reported more behavior problems.

The only significant treatment effect on health status was seen in the mother's report of the child's morbidity, with higher morbidity scores reported for the lighter-weight children in the intervention group (ES=0.29, p<.001). No group differences were reported among the heavier-weight children. This finding was significantly influenced by maternal age: Children of younger mothers in the intervention group had more reported morbidity than children of younger mothers in the followup group. This difference was accounted for entirely by brief, nonserious illnesses.

In summary, we conclude that the comprehensive and intensive early intervention program in the Infant Health and Development Program produced substantial benefits for low birthweight premature infants. The study is particularly important because, in contrast to previous single-site studies, it was implemented in eight geographically distinct locations with great demographic variation. Despite this heterogeneity, the program was significantly effective overall and in seven of the eight sites. Thus, there is strong evidence that the program may be generalized to many communities.

Recommendations

Following are the recommendations resulting from the study:

- 1. High quality, comprehensive followup programs for low birthweight premature infants should be incorporated into medical care plans, particularly for infants suffering the dual handicap of low birthweight and social disadvantage.
- 2. Data from this study should be made available as guidelines for providing intervention programs for high risk infants.
- 3. This cohort of low birthweight premature infants which has been so carefully studied and documented through age 3 should be followed with the same care well into the school years in order to assess the long-term benefits of this intervention.



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10

26

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Presentations

None to date.



HEALTH AND NUTRITIONAL STATUS OF MEXICAN-AMERICAN CHILDREN

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 Costs*
 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 Awarded
 255,734
 288,478
 no cost
 n/a
 n/a

extension

Requested 255,734 288,478 no cost n/a n/a

extension

SUMMARY

Statement of the Problem

The Mexican-American population is the most rapidly growing ethnic group in the United States. It is also a young population, with approximately 40 percent of the Mexican-American population under 18 years of age. Furthermore, the 1987 census showed that 26 percent of Mexican-American families live below the Federal poverty level. These demographic characteristics suggest that a large proportion of Mexican-American children may be at risk for poor health because of their poverty status. Greater attention should be directed toward the health care needs of these children. Effective policies can be developed only with accurate information about the health care needs of these children. Unfortunately, documentation of the health status of Mexican-American children has been limited. Studies are needed that will provide information on their growth and nutritional status, and the prevalence of chronic and acute diseases among these children. It is important to examine the health risk factors common to these children, as well as their access to and use of health care services. Only with this information can effective policies be developed to meet the health care needs of this population of children.



^{*} Indirect included

Research Questions or Hypotheses

The purposes of this study were to:

- 1. Identify and quantify the health and nutritional problems of Mexican-American children relative to those found in other Hispanic and non-Hispanic children;
- 2. Measure time trends in key aspects of health and nutritional status in the Mexican-American population;
- 3. Identify the correlates of poor health and nutritional status, particularly with respect to poverty and acculturation; and
- 4. Identify major constraints to the use of health and nutrition services.

Study Design and Methods

This study analyzed data from health surveys conducted by the National Center for Health Statistics. Analyses were performed using the Statistical Analysis System and specialized software packages to correct for the multistage complex sampling design of the surveys. Assistance was provided by the staff of the National Center for Health Statistics, Division of Health Examination Survey. National norms for selected variables were used for comparisons, and these were obtained from the National Center for Health Statistics, the Centers for Disease Control and Prevention, and the National Institutes of Health. Where reference data were not readily available, normalized standards for non-Hispanic whites from the National Health and Nutrition Examination Surveys (NHANES) were used.

The health status of Mexican-American children was evaluated by determining the prevalence of medical conditions, poor health perception, low birthweight, and poor dental health. Nutritional status was assessed by dietary intakes, iron status, and anthropometry. Finally, the evaluation of health care utilization by Mexican-American children was assessed by the reported use of health services for routine and sick visits.

Study Sample and/or Population

Data were drawn from the National Health and Nutrition Examination Survey 1971–1973 (NHANES I), the Second National Health and Nutrition Examination Survey 1976–1980 (NHANES II), and the Hispanic Health and Nutrition Examination Survey 1982–1984 (HHANES). In the NHANES I and II, a population of children under age 18 was identified, comprising 796 Mexican-Americans; 444 other Hispanics; 9,935 non-Hispanic whites; and 2,754 blacks. From the HHANES, only data on Mexican-Americans from the Southwest (3,677) were included in the study. Although the primary data set was the HHANES, NHANES I and II were used to refine hypotheses for HHANES and to examine secular trends in selected health and nutritional status parameters.

Findings

Some of the findings presented below are preliminary; further analyses are currently under way in the continuation grant.

1. Nutritional status: Only the dietary intake frequency data were available from HHANES; therefore, actual caloric and nutrient intakes could not be determined. The dietary intake frequency data did, however, suggest that the diets of Mexican-American



children and adolescents may be lacking, particularly in the frequency of breads, fruits, and vegetables. This was most prominent for adolescents. Determining whether these children are getting adequate nutrition will have to await the release of the 24-hour dietary recall data from HHANES.

The measures of iron status suggest that Mexican-American children and adolescents in general have a status similar to that of non-Hispanic whites, and that their status has improved over the past decade. The prevalence of iron deficiency anemia among children under 3 years of age has fallen to 2.0 percent. The only age group of Mexican-Americans that has not improved in iron status is that of adolescent females.

The anthropometric measures of Mexican-American children in HHANES demonstrate that poverty is a major determinant for height but not for weight in children under 12 years. After age 12, ethnicity is a better predictor of height. This has suggested a possible cohort effect with respect to height. This hypothesis is supported by the improvement in mean heights for Mexican-American children over the past two decades.

The normal distribution of weight for these children has led to a short and stocky physique. In turn, the prevalence of obesity seems to be higher among Mexican-American children than among non-Hispanic white children. This increased obesity is unrelated to poverty status.

Sexual maturation of Mexican-American adolescents is slightly delayed both in onset and completion. These data, however, must be viewed cautiously until longitudinal data are available.

2. Health service utilization: Utilization seems to be adequate for three-fourths of Mexican-American children. This includes the use of both routine and sick visit services. About 90 percent are reported to have a regular health care site, and 80 percent of the children's mothers are very satisfied with the care. Among those mothers who do not have a regular health care site, however, the most common reason cited for not having one is lack of need for a doctor. Yet, the most common reason for not obtaining health care is lack of money. There appear to be both access and utilization problems for Mexican-American children. This is further suggested by the finding that, although developmental-behavioral medical conditions are common among these children, they are undertreated in comparison to physical disorders.

Hospitalization has occurred among approximately 20 percent of the children, and length of stay for two-thirds of these hospitalizations was 1 night.

Seventy-six percent of adolescents reported a regular health care site. Those with a regular health care site reported adequate usage of health services, while those without such a site reported underutilization. Twenty-two percent of the adolescents without a regular site had not been seen by a physician in the past 5 years, and an additional 30 percent had not been seen by a physician in 1–5 years. Moreover, 34 percent of all adolescents had not had a preventive health care visit within the past 5 years. These data suggest a significant underutilization problem among Mexican-American adolescents.

Most adolescents were satisfied with their care. The lack of need for a physician was most commonly stated as the major reason for not having a regular health care site. Those who could not obtain health care most commonly stated that cost of care was the reason. Only 7 percent of adolescents reported a hospital stay in the past year, and 86



percent of these stayed for 1 night. Lastly, less than 2 percent of children and adolescents reported use of folk healers.

Overall, health care utilization appears to be a significant problem for about 25 percent of Mexican-American children and adolescents.

3. Health status: Data from NHANES II demonstrated that Mexican-American children have had a prevalence of mild, moderate, and severe medical conditions similar to those of non-Hispanic white children. Among Mexican-American children, the prevalence of mild, moderate, and severe medical conditions was 39 percent, 36 percent, and 3 percent, respectively. HHANES assessed only the prevalence of chronic medical conditions (3.86 percent). This prevalence was similar to that of severe medical conditions in NHANES II for non-Hispanic white children; this implies that these two populations do not differ in the prevalence of severe chronic medical conditions. Less severe conditions were not assessed in HHANES.

Types of medical conditions could be assessed with some accuracy only in the HHANES. These data showed that cardiovascular disorders, mental/central nervous system disorders, and congenital anomalies were the most common, but appeared to occur with about the same prevalence as for non-Hispanic white children. Neither poverty nor acculturation appears to have any effect on the prevalence of chronic medical conditions.

Specific, targeted medical conditions were also assessed in HHANES (by interview only, not by physician's examination). Overall, these reported medical conditions appeared to be at similar prevalence rates as reported for non-Hispanic white children. An interesting finding is that, among those targeted medical conditions which were still present at the time of the survey, 31 percent of children ages 6 months to 4 years and 40 percent of children ages 5–11 had developmental-behavioral conditions. Data on reported medical conditions for adolescents were restricted by a focus on adult diseases; therefore, useful information on conditions concerning adolescents was limited.

There was a significant difference between Mexican-American children and non-Hispanic white children in health perception. The health status of the child or adolescent was rated by survey physicians, mothers, and the children and adolescents themselves. Physicians rated only 1 percent of children and adolescents in poor health. Their ratings were affected primarily by the presence of a chronic medical condition and only minimally by poverty. In contrast, mothers', children's, and adolescents' ratings of poor health were significantly higher (10–30 percent). Although mothers' and adolescents' ratings were affected by the presence of a chronic medical condition, poverty and acculturation appeared to be more prominent as determinants of a poor health rating by both of these groups. For children under 12, poverty, acculturation, and the presence of a chronic medical condition were not found to be significant determinants.

According to the mothers, 5.6 percent of children were reported to have had a birthweight less than 2,500 grams. This low birthweight rate is similar to that for non-Hispanic white children.

Dental health for Mexican-American children was found to be significantly worse than for non-Hispanic white children. Although total dental needs for primary teeth were similar for Mexican-American and non-Hispanic white children, Mexican-American



children had more severe diseases. Mexican-American adolescents also had greater dental health needs and more severe dental diseases.

Recommendations

Further work involving the HHANES is currently under way, including further analyses of the Mexican-American sample and the Puerto Rican and Cuban samples. Current conclusions and recommendations are preliminary.

The most prominent factor affecting the health of Mexican-American children is poverty. Therefore, programs aimed at buffering the effects of poverty would appear to be needed for this population of children. This includes programs that provide health and nutritional services. Health services should be directed at meeting the diverse needs of this population of children and should include developmental-behavioral conditions as well as dental health problems.

Adolescence seems to be a period associated with significant health and nutritional problems. Some of these problems may result from previous poor health periods and lack of access to health care, particularly preventive services. Therefore, increased emphasis on programs directed at these Mexican-American children should be considered.

Lastly, culture and the process of acculturation seem to play a role in the health of Mexican-American children and adolescents. Further work is greatly needed in this area to delineate the mechanisms involved and to determine whether culturally based behaviors can be protective for children living in poverty.

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PESTICIDE EXPOSURE AND PREGNANCY OUTCOME

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SUMMARY

Statement of the Problem

Knowledge of the toxic effects of specific environmental agents and their link to mechanisms of human reproduction is in its infancy. Although evidence indicates that pesticides can pass through the human placental barrier, further study is needed to document unspecified effects and to replicate the results found by current researchers. Spontaneous abortion, low birthweight, congenital anomalies, cleft lip and cleft palate, limb defects, and infertility have been the focus of some recent investigations. Many of those studies found that chemicals in the environment can contribute to the incidence of birth defects and other reproductive harm in the general population. The role of pesticides, in particular, may be significant. Few studies have focused on community exposures to pesticides, which tend to be lower than occupational exposures. Also, few population-based studies have attempted to determine the actual degree of exposure in individual cases.

This study investigated the reproductive effects of organophosphate and carbamate insecticides. Organophosphate pesticides are versatile, widely used pesticides which have replaced organochlorines in popularity since the 1970s. Their mechanism of toxic action is the inhibition of cholinesterase. Carbamate pesticides are similar to organophosphates in the action of inhibiting cholinesterase, but are generally less toxic because they have a shorter life. This study included an examination of environmental and occupational



^{*} Indirect included

exposures, and made an assessment of degree of exposure through use of repeated measures.

In this study, the protocol for ascertaining pesticide exposure was incorporated into routine prenatal care. The value of this approach is that it demonstrates the feasibility of monitoring pesticide exposure routinely in pregnancy when environmental or occupational risk is suspected. Additionally, in areas where there is a high volume of pesticide use per acre, a standard protocol for collection of blood samples to test for cholinesterase (to use as a baseline value) could be recommended to providers who care for women preconceptionally (e.g., at family planning clinics). In addition to having immediate utility, such data will be available for retrospective analysis of outcomes occurring over the years of growth and development of the offspring born to these women. For women who are already pregnant, the collection of biologic samples for cholinesterase baseline values could be implemented at the postpartum visit.

Research Questions or Hypotheses

The study tested the following hypotheses:

- 1. There is no difference in the blood cholinesterase activity between women who report exposure to pesticides during pregnancy and women who report no exposure.
- 2. There is no difference in the occurrence of spontaneous abortion between women who have been exposed to cholinesterase-inhibiting pesticides and those who have not been exposed.
- 3. There is no difference in the occurrence of preterm labor between women who have been exposed to cholinesterase-inhibiting pesticides and those who have not.
- 4. There is no difference in the occurrence of low birthweight infants between women who have been exposed to cholinesterase-inhibiting posticides and those who have not.
- 5. There is no difference in the occurrence of toxemia of pregnancy between women who have been exposed to cholinesterase-inhibiting pesticides and those who have not.

Study Design and Methods

A prospective cohort design was used. The study followed a cohort of 535 women throughout their pregnancies, through interviews on history of exposure, collection of biologic specimens, and review of maternal and newborn records. Biologic specimens were used to verify the pesticide exposure experience (exposed versus nonexposed) of the cohort members as reported in interviews. Data from maternal and newborn patient records were used to verify previous health and reproductive history and to determine current pregnancy outcome. Comparisons of the pregnancy cholinesterase activity and of selected pregnancy outcomes were made between the two exposure groups.

Three assessment measures were used: A questionnaire (consisting of three modules) to determine self-reported exposure history and potential confounding variables; maternal patient records (primarily the Hollister Prenatal Record System) and



newborn patient records; and biologic assay of blood samples for cholinesterase activity in red cells and plasma. Some fetal cord blood assays were also carried out.

The questionnaire items addressed residential/environmental exposures, the occupational history of the participant and spouse, specifics of potential exposures, pesticide handling and use, and prescription and nonprescription drugs, alcohol, and smoking history. The questionnaire was pretested in Spanish and English in order to determine whether it met expectations for participant comprehension and whether the interviewers would understand how to ask questions and record the responses accurately.

There were eight data modules in the complete data set, three of which were included in the questionnaire (the master data form, initial interview and assessment, and ongoing exposure assessment). The other five modules (health history summary, reproductive history, nutritional assessment, birth outcome, and laboratory) were completed primarily by patient record review.

The Hollister Prenatal Record System was used for the study subjects. This system is designed to identify women at risk for a problem pregnancy, based on their current medical condition and their socioeconomic history. It is widely used and is a standard, accepted system among prenatal and perinatal obstetric practitioners. Newborn and birth outcome information was abstracted from hospital records at the facility where delivery occurred.

Maternal blood samples for determination of cholinesterase activity were taken at the time of the initial interview, and at each followup interview for a total of three samples per participant, approximately one per trimester. Postpartum sampling was instituted toward the end of the second project year to serve as a possible baseline (nonpregnant) value. The simultaneous timing of the interview and the blood sampling was to insure maximum congruence between the exposure verification methods.

Study Sample and/or Population

The study population was composed of women enrolled in the North County Health Services (NCHS) Perinatal Program. All attended NCHS clinics in northeastern San Diego County. They were primarily Hispanic women of low income and low educational status, and many had recently emigrated from Mexico. The average age of the participants was in the mid-twenties, and the majority had more than one child. Because agricultural production in northern and eastern San Diego County is among the highest in the State, these women are considered to be potentially exposed, occupationally and/or environmentally.

The NCHS Perinatal Program serves approximately 300 pregnant women each year. The study was described verbally and in writing (in the women's native language) to all patients entering the perinatal program between January 1987 and December 1989. They were then asked to participate. Those who agreed to participate signed informed consent forms. Approximately 75 percent of the women entering the clinic during this period participated in the study. There is no difference in the sociodemographic and reproductive characteristics between those who agreed to participate and those who did not.



Findings

The expectation was that the mean plasma cholinestorase levels would be higher among the non-exposed than the mean for the entire group, and that the levels among household- and agricultural-exposed women would be lower than those of the nonexposed women and lower than the mean for the entire group. This was found to be the case. Consistently, the exposed women's monthly mean levels of cholinesterase were lower than those of the total study group, and the nonexposed group's mean levels were consistently higher than the mean. Graphically, the trends indicated differences, although these differences were not statistically significant between the monthly group means, except for month 6 (p=.037). Household exposure levels ranged from .5 percent to 4 percent lower than the mean group. Agricultural exposure levels ranged from 1 percent to 4 percent lower than the mean group. The mean levels of women who reported no exposure to pesticides were 2 percent higher than those of the mean group.

The expectation was that subjects with plasma cholinesterase in the low end of the group distribution would fall in the household-exposed or agriculturally exposed groups. The overall correspondence between relative plasma cholinesterase activity and selfreported pesticide exposure classification was statistically significant (p < 0.01). For a sample of 207 subjects, approximately half (51.2 percent) of the low cholinesterase group were classified by self-report as nonexposed and half (48.8 percent) as exposed to agricultural or household pesticides, with more reporting exposure to agricultural (31.4 percent) than household (17.4 percent) pesticides. In this group, an individual with low cholinesterase may or may not have reported any pesticide exposure. However, examination of column totals reveals that the majority of nonexposed subjects (61.7 percent) did have either intermediate or high cholinesterase, and the majority of agriculturally exposed subjects (52.9 percent) had low cholinesterase relative to the entire sample. Equal numbers of subjects (40-45 percent) exposed to household pesticides fell into high and low cholinesterase groups. Using these classification categories, the plasma levels can help confirm the self-reported classifications but cannot be used alone to "predict" what the self-report would have been with a high level of certainty.

Among the 374 women for whom data were available, there were 8 spontaneous abortions (2.1 percent). This rate is much lower than the expected rate of 15 percent of all medically recognizable pregnancies. The relative risk analysis for exposed to nonexposed showed no effect of exposure.

Several approaches to categorizing low birthweight were used in the analysis of the association between maternal pesticide exposure and birthweight. This was necessary because the occurrence of births of 2,500 grams or less was 3.1 percent, well below the expectation of 6.8 percent for the United States. Four ways of categorizing low birthweight were used: 2,500 grams or less; 3,000 grams or less; above the mean; or below the mean. None of the relative risks show statistically significant differences in risk of low birthweight for exposed versus nonexposed women. By all definitions used for low birthweight, there is a greater incidence of low birthweight among the nonexposed. The relative risk point estimate is less than 1.0.

Among the 374 study subjects in this analysis, there were 40 cases of toxemia (10.7 percent). This rate is somewhat higher than the expected rate of 7 percent for all



pregnancies not terminating in first trimester abortion. The relative risk analysis, however, does not show a difference in risk between the exposed versus the nonexposed. Based on their medical, reproductive, and social history, women who had toxemia and who were exposed to pesticides were also more likely to have been assessed at risk for complications during the current pregnancy (98 percent compared to 58 percent).

The incidence of preterm birth was 5.6 percent, compared to an expected rate of 8.9 percent. No difference was detected in the relative risk for exposed versus nonexposed women.

Recommendations

The following recommendations have resulted from the study:

- 1. Incorporate into routine prenatal care a protocol for detecting and monitoring pesticide exposure;
- 2. In high volume pesticide areas, incorporate a standard protocol for blood sampling to determine cholinesterase baseline values among preconceptional women. These values will be the markers for detecting cholinesterase changes in pregnancy;
- 3. Institute educational programs about safe use of pesticides for pregnant women and for those who are planning a pregnancy (due to the high prevalence of household pesticide use); and
- 4. Develop research studies on reproduction, which, by their design, are able to pinpoint time of exposure and quantify actual exposure levels.

PUBLICATIONS

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Abstracts

None to date.

Presentations

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Walker C, Willis W. Pesticide exposure interview and education in a prenatal clinic. Presented at the American Public Health Association Meeting, New York, NY, September 30–October 24, 1990.

Walker C. Health and behavioral risk factor differences in a prenatal population. Presented at the American Public Health Association Meeting, New York, NY, September 30–October 24, 1990.

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A SURVEY OF CHRONICALLY ILL CHILDREN'S USE OF TIME OUT OF SCHOOL

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* Indirect included

SUMMARY

Statement of the Problem

Today, about 1 million children are living with a severe chronic illness and another 9 million have less severe chronic illnesses. The goal for the care of these children is to help them achieve their full potential for functioning in society. Therefore, the consequences of the disease for the physical, psychological, and social functioning of the child are an important concern for health care providers. The assessment of physical and psychological abilities and meaningful interventions at regular intervals are now of critical importance to the comprehensive management of chronically ill children and their families. However, while American society is geared to almost unlimited support of medical technology, there has been a significant lag in understanding the functional consequences of chronic illness for children. The need for research to address these issues and therefore enable health care personnel to provide care that ameliorates the psychosocial effects of chronic illness has been addressed by the American Academy of Pediatrics, the U.S. Surgeon General, and the Vanderbilt Study of Chronically Ill Children and Their Families.

The primary aim of this study was to describe and analyze the everyday out-of-school life experiences of chronically ill school-age children and to examine the effects of different ecological contexts on the child's out-of-school life. To accomplish this aim, we focused on the ways in which chronically ill children use their out-of-school time. The use of time is a proxy—an indicator of what matters to children and to their parents.



Research Questions or Hypotheses

This study addressed the following research questions:

- 1. What kinds of things do chronically ill children do when they are not in school?
- 2. What are the effects of family life, family structure, and socioeconomic status on these children's lives outside of school?
- 3. What are the range of opportunities and constraints that shape children's use of time and their attitudes toward time use outside of school?
- 4. What roles do neighborhoods have in the out-of-school activities of chronically ill children?
- 5. What is the capacity of urban environments to serve as support systems to parents directly involved in planning and managing chronically ill children's use of time out of school?

This study tested the following hypotheses: (1) The pattern of chronically ill children's time use outside the home depends on the extent and manner in which parents and others engage in joint activities with the child; and (2) the capacity of the parents to engage in such joint behavior depends on the extent to which external support systems exist to provide opportunity, assistance, resources, and channels of communication.

Study Design and Methods

A cross-sectional survey design was used to collect data at one point in time from a sample of 365 chronically ill school-age children and their parents. We examined time use in five areas: Children's activities on their own (alone or with friends); children's activities with their parents; children's in-home and out-of-home chores, jobs, and responsibilities; children's participation in organized activities; and television viewing. These were activities that would be meaningful to children from a wide range of backgrounds, and represent different aspects of daily life for a school-age child.

Data were collected using three instruments. The child's questionnaire consisted of 59 multiple choice items which evaluated time use in the five domains. The parent's questionnaire consisted of 83 multiple choice items which evaluated the parent's values, attitudes, and opinions in six areas (the neighborhood, the child at school and home, child's activities with family and friends, organized after-school activities, child rearing and parents' activities). The parent also completed an 18-item medical questionnaire which obtained background information about the child's illness and treatments.

All interviews were conducted in the child's home. The child was interviewed by a female interviewer while the parent completed the parent questionnaire. Data collection and data coding were managed by the Survey Research Center, University of California at Berkeley.

Study Sample and/or Population

The study sample was drawn from the population of chronically ill school-age children residing in the San Francisco and Birmingham Standard Metropolitan Statistical Areas. A noncategorical approach focusing on disease commonalities was used, enabling selection of children with a variety of chronic illnesses.



Guidelines by Kish on the strategies of large clusters and controlled selection were used in developing the sampling frame. Subjects were children ages 10–12 who (1) were diagnosed as having an organic chronic illness for at least 2 years, (2) were attending school, and (3) had not moved or changed schools in the past year.

The sample, stratified based on socioeconomic status, consisted of 365 children and their parents (209 from San Francisco, 158 from Birmingham) randomly selected from a sampling frame of 937. The overall sample was well distributed with regard to age, gender, and race. Children ranged from 9 to 13 years of age. For purposes of analysis, 9-year-olds were grouped with 10-year-olds, and 13-year-olds were grouped with 12-year-olds. This was done because the children were either approaching their 10th birthday, or had only recently celebrated their 13th birthday.

The age distribution of the sample was as follows: 30 percent were age 10 years, 25 percent were age 11, and 38 percent were age 12. Fifty-eight percent were male and 42 percent were female. Subjects were predominantly white (59 percent) and African American (24 percent); 5 percent were Asian and 4 percent were Hispanic. Seven percent of the respondents in the California sample declined to state their race.

Children in the sample had chronic illnesses representing 10 diagnostic categories: Asthma (27.96 percent), congenital heart disease (17.93 percent), neuromuscular disorders (11.74 percent), diabetes (11.10 percent), seizure disorders (11.10 percent), renal disorders (6.19 percent), juvenile rheumatoid arthritis/systemic lupus (5.44 percent), sickle cell anemia/blood disorders (4.80 percent), cystic fibrosis (3.63 percent), and growth hormone disorders (0.11 percent).

Findings

Each out-of-school time-use domain was characterized by a pattern of its own. No single background variable or single set of variables consistently explained patterns of behavior.

Children individually and with friends engaged in a variety of activities. With friends, chronically ill children were more likely to engage in physically active pursuits; when alone, they were more likely to engage in more passive activities. Boys were more likely to engage in physically active activities, and girls were more likely to play indoors with small groups of friends. Most children played close to home. A high percentage of the children (26 percent) could not name a close friend, and 25 percent admitted playing alone most of the time.

The children and parents engaged in a number of activities together. White, two-parent families and high-income families went more places together. Single-parent families (in which the mother worked) tended to go fewer places outside the home. Parents' education and family income influenced the type of places parents and children went. Better educated, upper-income parents were more likely to visit libraries and museums, and to attend cultural events, while less educated and lower-income families went to public recreation areas and sporting events. Family activities did enhance the skill development in the children.

Latchkey children (children home alone without adult supervision) accounted for 28 percent of our sample. Maternal employment, family structure, and family income were all related to the likelihood of latchkey status.



Only 12 percent of the children in our sample reported working outside the home on a regular basis. However, 88 percent reported that they had some chores to do around the house. Children perceived as seriously ill were the most likely to have no chores.

Eighty-seven percent of the children in our sample reported receiving spending money from parents. However, only 17 percent reported saving their money.

The vast majority of the children engaged in an organized activity after school: 56 percent of the children took after-school lessons, 34 percent participated in team sports, and 49 percent participated in a school activity. Middle-income children participated in more school and organized activities, while high-income children participated in more after-school lessons, team sports, and organized groups. Low-income children reported less participation in any organized activity. Participation in activities was greater for children whose mothers had higher levels of education. Children who were severely ill participated in more school activities than after-school activities.

The domain most integrated into daily life was television time use. Family characteristics of children who were heavy viewers included the following: Lower-to-middle income, lower levels of maternal education, and single parent families where the mother was unemployed. Children who were heavy viewers had mothers who reported increased concerns about neighborhood safety. As the mother's perception of severity of illness increased, so did the frequency of permissive rules about television viewing.

Overall, the sample children averaged 51 minutes per day for treatments. Mothers were primarily responsible for medical treatments and maintenance of medical equipment. Fathers helped about 10 percent of the time; siblings' help was negligible. The mean number of days of school missed was 11.3. Thirty-five percent of the children had experienced recent discriminatory acts.

Recommendations

To create environments that are conducive to the health, growth, and development of chronically ill children and their families, we propose that health care providers and policymakers address the following topics:

- 1. Lack of flexibility in the work environment;
- 2. Lack of flexibility in the health care system;
- 3. Heavy time burdens and demands on mothers of chronically ill children;
- 3. Lack of child care programs for school-age children;
- 4. Need for a national policy for families with chronically ill children; and
- 5. Support for the right of chronically ill children to a stimulating, developmentally appropriate environment.

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INTERACTION AND SUPPORT: MOTHERS AND DEAF INFANTS

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SUMMARY

Statement of the Problem

Deaf children with hearing parents are known to be at risk for language delays, academic underachievement, and emotional-behavioral disorders. Early intervention increases performance levels, but difficulties in the detection of congenital deafness have delayed application of audiological and educational expertise. Recent advances in diagnostic procedures and practices mean that more infants are identified early, but little research has been done on the developmental impact of early hearing loss because of difficulties in finding suitable numbers of subjects.

While little research has been done with hearing-impaired babies, there has been an enormous expansion in knowledge about infants generally, and particularly about their capacities to regulate social and affective interaction, to respond to environmental stimuli, and to affect the environment by their responses. Knowledge about the process of language acquisition also has grown exponentially.

This research project was designed to investigate the impact of early auditory loss on early mother-infant interaction, on infants' motivation to master the environment, their social coping skills, and their prelinguistic development. These developmental domains were viewed in the context of the family stress created by the diagnosis of deafness and the network of social support available to parents.

Research Questions or Hypotheses

The purposes of the study were to provide (1) basic developmental information to behavioral scientists, and (2) a basis for informed intervention to parents and educators responsible for the early care of hearing-impaired infants.



Study Design and Methods

Twenty normally developing hearing-impaired infants were recruited, and normally hearing infants were matched with that group for gender and mother's education. Infants' hearing losses were diagnosed by the age of 7 months. Fifteen had hearing losses in the severe to profound range, and 5 had losses that were less severe.

Data were collected when infants were 9, 12, 15, and 18 months of age. The 15month contact was a home visit for the purpose of interviewing the mother; other contacts were in a laboratory at one of the five research sites.

At the 9-month visit, mother and infants were videotaped in a standard Face-to-Face interaction format, with two 3-minute intervals of normal interaction separated by a Still-Face episode where mothers were instructed to be nonresponsive. Mastery Motivation was assessed by the presentation of four age-appropriate toys. An interview was conducted and questionnaire data on family stress and support were collected.

During the 12-month visit, Mastery Motivation was assessed a second time; mothers and children participated in a 15-minute unstructured play session, and in the Ainsworth Strange Situation Procedure, a standard laboratory procedure for assessing infants' attachment to their mothers through a series of brief separations and reunions.

At 18 months, mothers and children were again engaged in the Ainsworth Strange Situation Procedure and in 20 minutes of free play. Another interview was conducted and additional questionnaire data collected.

Study Sample and/or Population

Twenty normally developing hearing-impaired infants were recruited from 5 metropolitan areas; normally hearing infants were matched with the deaf infants for gender and mother's education. Infants' hearing losses were sensorineural and at least in the moderate range. Families were mostly white, middle class, and college educated, but subjects were not excluded because of race, ethnicity, or socioeconomic class. All babies within the five metropolitan areas who were diagnosed as deaf but who had no additional handicaps were recruited. Extensive contacts with medical, audiological, and educational service professionals were organized by each research group, in an effort to initiate referrals to all newly diagnosed infants.

Findings

On several measures, families with deaf infants reported significantly higher levels of stress and higher levels of social support. Differences in stress levels were accounted for primarily by stress related to care of the newborn child; differences in support levels were accounted for by services provided by intervention specialists.

Infant mastery motivation: Deaf and hearing infants did not differ in their persistence in efforts to master objects, at either 9 or 12 months of age. However, social gaze behaviors directed to the examiner or to the mother at 9 months predicted mastery motivation (persistence) at 12 months for the deaf (but not the hearing) infants.

Infant social coping skills: At age 9 months, hearing infants were more likely to elicit responses from their mothers during the Still-Face situation, while deaf infants were more likely to exhibit self-comforting behaviors. This was interpreted as reflecting a tendency



to internalize their discomfort, compared to the hearing infants' more active efforts to repair the disrupted interaction. At 18 months, there were no differences between the deaf and hearing infants' quality of attachment to their mothers. On the basis of more specific subcategories of behavior, deaf infants responded to separation by exhibiting greater avoidance at the reunions, compared to the hearing infants.

Infants' communicative abilities: Deaf and hearing infants did not differ in their production of prelinguistic visual-gestural communication, in the quantity of vocal communication, or in frequency of intentional communication either at 12 or 18 months. The quality of hearing infants' vocal productions and their formal language levels exceeded those of the deaf infants.

Mother-infant interactions: At 9, 12, and 18 months, mothers with deaf infants exhibited a positive adaptation to infants' auditory deprivation by providing more visual cues than did mothers with hearing infants. However, at 9 months, mothers with hearing infants were judged to be more responsive to their babies (in the Face-to-Face format), and, at 18 months, mothers with hearing infants were judged to be more sensitive to their babies (in the free play setting) compared to mothers with deaf infants. Spoken language of mothers with hearing infants was more contingent on infants' visual attention at 12 and 18 months, compared to the spoken language of mothers with deaf infants.

Development of mother-infant interaction and language from 9 to 18 months of age: Based on results of previous research, we had predicted that the groups of hearing mothers with deaf and with hearing infants would display varying patterns of interaction and mastery motivation at ages 9 and 12 months, and that these patterns would predict differences in the quality of mother-infant interaction and in infants' language levels at 18 months. We also predicted that these patterns of interaction and language development would be specified by family stress and social support. These hypotheses were tested by two sets of multiple regressions.

- 1. Quality of mother-infant interaction: Based on qualitative ratings of mothers and infants at 18 months, a global score was assigned to reflect the overall quality of dyadic interaction. Four predictor variables were identified: Family social support; infant social smile during Mastery Motivation assessment at 9 months; infant gaze turned away during the Still-Face episode of Face-to-Face interaction at 9 months; and mother responsiveness during normal Face-to-Face interaction at 9 months. These four variables accounted for 29 percent of the variance in interactions of dyads with hearing infants and 79 percent of the variance in interactions of dyads with deaf infants at 18 months. Of special note is the strong positive impact of family social support on the quality of interactions between mothers and deaf infants.
- 2. Infants' language level: The second outcome measure was an infant language level index from the 18-month communication data. Two predictor variables were identified for this measure: Mother-infant affective match, and mothers' visual-tactile responsiveness (both from Face-to-Face data at 9 months). These variables accounted for 37 percent of the variance in language level for the hearing infants, but none of the variance in the language levels of the deaf infants. However, the mothers' visual-tactile responsiveness had a negative relationship with the hearing infants' language performance.



Recommendations

Recommendations resulting from the study address policy, intervention, and research.

1. Policy: Programs for earlier detection of hearing loss should be broadened and intensified. Child find procedures with immediate referral to intervention programs should be a goal with high priority in every jurisdiction. Our research shows that hearing loss influences development from the earliest months, and that intervention, especially support services for families, has a positive impact on adaptation.

2. Intervention:

- a. Medical doctors, especially pediatricians, should be better informed of the benefits for deaf infants and their families of immediate psychoeducational intervention. Efforts should be made to create referral networks for medical and educational specialists.
- b. Special efforts should be made to find and provide services for disadvantaged, minority families, whose infants appear to be least likely to receive early identification.
- c. Increased emphasis should be placed on providing social and emotional support to families immediately after diagnosis of an infant's hearing loss. Our research shows this to be an important predictor of optimal mother-infant interaction.
- d. Intervention programs should incorporate information on the importance of language contingent on infants' attention focus and appropriate for visual processing into their work with parents.

3. Research:

- a. Additional research is needed with disadvantaged families who were not represented in this research project. Studying a population of deaf infants with deaf parents would add important dimensions to our understanding.
- b. Research to enhance understanding of the visual processing of deaf infants is important.
- c. Additional research is recommended to enhance understanding of alternative communicative modes for deaf infants, particularly tactile and visual responses optimal for parent-infant interaction.

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58

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Intravenous Antibiotic Therapy in Cystic Fibrosis: Home Versus Hospital

GRANTEE

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PROJECT NUMBER

MCJ-220556

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Costs*

Year 1 Year 2 Year 3 Year 4 Year 5 301,586 377,434 475,272 denied n/a 301,586 400,813 429,312 45,988 n/a

SUMMARY

Statement of the Problem

Over the past 50 years, the average life expectancy for a person with cystic fibrosis has risen from under 5 years of age to between 20 and 25 years of age, due in large part to improvements in antimicrobial therapy, particularly the use of intravenous antibiotics. However, because of the chronic, progressive nature of their lung disease, these patients experience longer and more frequent hospitalizations as they get older.

Administration of intravenous antibiotics at home has become a popular alternative to hospitalization in the past decade. Results from preliminary studies have indicated that home intravenous antibiotic therapy might reduce the need for hospitalization without compromising care. However, no prospective, randomized, controlled trials have been performed to establish the safety, efficacy, patient acceptance, and cost of this type of therapy.

Research Questions or Hypotheses

The purpose of this study was to compare both short-term (2 week) and long-term (1 year) effects of home intravenous antibiotic therapy with those of traditional hospital IV antibiotic therapy on patients with cystic fibrosis who were having an exacerbation of pulmonary disease. The effects of the two therapies on the study population were compared in five major areas: Efficacy, safety, acceptance by patients and parents, psychosocial effects on patients and parents, and cost.



^{*} Indirect included

Study Design and Methods

This study was a prospective, multicenter, randomized, controlled clinical trial. Study patients were identified at the beginning of an exacerbation of pulmonary disease and screened for inclusion in the study by a physician and a nurse or social worker. If patients were found to be suitable and agreed to participate, they were randomized to either hospital therapy or home therapy after a short period of hospitalization, and each patient was followed for 1 year after enrollment. Data were collected during the initial exacerbation, during each subsequent exacerbation, and at clinic visits 6 and 12 months after enrollment. At these times, each patient had a chest roentgenogram, a complete physical examination, and pulmonary function tests that include forced expiratory volume (FEV₁), forced vital capacity (FVC), and the maximum rate of catalysis (Vmax₅₀).

Patient acceptance of treatment was measured by questionnaires given to participants at the end of the first exacerbation and at the 12-month visit, and by determining the percentage of patients who completed their assigned treatment course in each group and the percentage of those having a second exacerbation who agreed to stay in their assigned group for treatment.

Anxiety and self-concept in patients and caretakers were measured by the Piers-Harris Children's Self-Concept Scale, the Tennessee Self Concept Scale, the State Trait Anxiety Inventory for Children, and the State-Trait Anxiety Inventory. Coping skills of the caretakers were measured by the Coping Health Inventory for Parents.

Costs compared in the study were limited to three areas: Hospital or home-care company charges, physician charges for hospital care, and personal out-of-pocket expenses incurred by the patient and family during periods of IV antibiotic therapy either in the hospital or at home.

All patients received both an intravenous aminoglycoside (usually tobramycin) and an anti-pseudomonal penicillin or cephalosporin (usually ceftazidime) every 8 hours during a pulmonary exacerbation. For patients randomized to home therapy, a primary caretaker was identified and taught the techniques for storage, preparation, and administration of the antibiotics. The patient and family were put in touch with a home-care company that sent nurses to evaluate the patient every 4 days. Patients in home therapy were hospitalized for at least 3 days during the initial exacerbation and any subsequent exacerbations. In both groups, duration of treatment was a minimum of 10 days.

Study Sample and/or Population

Twelve centers participated in the study. In addition to Tulane University, the other centers were: Arkansas Children's Hospital, Little Rock, Arkansas; Children's Hospital of Los Angeles, California; Hahnemann University, Philadelphia, Pennsylvania; Louisiana State University School of Medicine, Shreveport, Louisiana; St. Francis Hospital and Medical Center, Hartford, Connecticut; University of Alabama at Birmingham, Alabama; University of Florida at Gainesville, Florida; University of Kentucky Medical School, Lexington. Kentucky; University of Nebraska Medical Center, Omaha, Nebraska; University of Rochester Medical Center, Rochester, New York; and University of Wisconsin, Madison, Wisconsin.



All study patients had cystic fibrosis, and at the time of admission to the study all were hospitalized with an exacerbation of pulmonary disease. Of 756 patients screened, 486 were potentially eligible; of these, 36 percent were excluded because of patient or family situations that precluded the safe administration of home intravenous antibiotic therapy. After inclusion and exclusion criteria were applied, 196 patients were eligible. Of these, 61 percent refused to participate and 39 percent (78 patients) were enrolled in the study. One patient agreed to participate and was randomized but then withdrew from the study. Thus, data were collected on 77 patients.

Findings

- 1. Following are the findings for the short-term component of the study:
 - a. Efficacy: No differences in treatment efficacy were found between the two groups over the course of the initial exacerbation, as measured by the primary outcome variable (FEV₁) or any of the secondary outcome variables.
 - b. Safety: No serious complications occurred in either group during the initial exacerbation. Similar numbers of minor complications were reported in both groups.
 - c. Acceptability: Of the 78 patients enrolled, 77 completed their initial treatment in the site to which they were randomized. Ninety-seven percent of home patients and 82 percent of hospital patients were willing to remain in the assigned group for future exacerbations.
 - d. Psychosocial effects: No significant differences (*p*>0.05) in mean psychological scores between the two groups were observed at baseline. The only area of difference over the first exacerbation appeared in the state/anxiety score for caretakers; this declined significantly for caretakers of home patients compared to caretakers of hospital patients.
 - e. Charges: Median total charges for hospital patients (\$13,169) exceeded that of home patients (\$10,678) by \$2,491 for the first exacerbation. The median length of treatment was 14.3 days in the home group and 12 days in the hospital.
- 2. The long-term data came from 71 patients who were followed for 1 year. (Four patients died before completing the study, and data on two were were incomplete and not used.) Following are the findings for the long-term components of the study:
 - a. Efficacy: No significant differences between groups were found in the long-term outcome variables measuring efficacy: Weight, NIH Score (p=.95), x-ray score (p=.22), FEV_IPP (p=.33), FVC (p=.57), and Vmax₅₀ (p=.27). In addition, no significant difference was found in the number of subsequent exacerbations.
 - b. Safety: Two patients in each group died during the study. Neither death in the home group appeared to be related to the use of home intravenous antibiotic therapy. No major complications occurred in either group; minor complications were similar in the two groups. Five patients in the home



- group experienced symptoms of possible drug reactions, three probably to ceftazidime and two to other drugs (p=.02). There were no differences between groups with respect to the appearance of pseudomonas organisms other than P. aeruqinosa or the development of resistance to tobramycin and ceftazidime.
- c. Acceptability: A total of 63 patients and/or caretakers filled in the exit questionnaire. The main advantage to home therapy cited was "normal activity," and the main disadvantages were "loss of sleep" and "extra work." The main advantage cited for hospital therapy was better care from professionals, the main disadvantage was "being away from home."
- d. Psychosocial effects: No clinically significant differences between the groups were detected in self-concept, state or trait anxiety, or in coping behavior.
- e. Charges: Median total charges for hospital patients (\$30,318) exceeded those of home patients (\$24,787) by \$5,531 (18 percent) for the year of followup. The length of treatment for hospital patients was 27 days, compared to 31 days for home patients.
- f. Savings: Savings in charges varied with length of stay in the home relative to total duration of treatment, with home-to-hospital charge ratio per day, and with the total duration of home-to-hospital treatment relative to hospital treatment alone. Home-to-hospital charge ratios in this study varied from 20 to 80 percent. Savings may accrue for long home stays relative to hospital stay when home-to-hospital charge ratios are less than 50 percent.
- 3. Patient recruitment was more difficult than expected, largely due to (1) inclusion and exclusion restrictions, (2) patient's preference for one type of therapy and consequent unwillingness to be randomized, and (3) patient's family or home environment considered unsuitable for the study by the team. Following are the findings relative to patient recruitment for the study.
 - a. Efficacy: Although home intravenous antibiotic therapy appears to be as effective as hospital therapy over 1 year of followup, it is possible that a small difference between the two would not become clinically apparent unless a larger group of patients was followed for a longer period of time.
 - b. Safety: Because six episodes of probable drug reactions were reported among home patients, we suggest that all patients should be observed in a medical setting for at least one or two doses of IV antibiotics before being sent home.
 - c. Acceptability: Almost two-thirds of study participants preferred home intravenous antibiotic therapy over inpatient care. However, the balance between advantages and disadvantages will depend on the individual family structure and resources, although disadvantages cited may diminish with new techniques for administering the antibiotics.
 - d. Psychosocial effects: No clinically significant adverse or beneficial psychological effects associated with home intravenous antibiotic therapy were demonstrated when compared with hospital therapy. However,



- moderate treatment differences may not have been detected, because of the small sample size in each age group tested.
- e. Charges and costs: Savings in charges varied with length of stay in the home relative to total duration of treatment, the total duration of home/hospital treatment relative to hospital treatment alone, and with the home-to-hospital charge ratio per day. There was wide variability of daily charges among centers (and, thus, of home-to-hospital charge ratios).

Recommendations

Our results indicate issues potentially relevant to other home parenteral programs characterized by intermittent but repeated treatment regimens. The following are examples of these issues: (1) The need to establish well-defined standards of care and followup for patients on home intravenous antibiotic therapy; (2) the desirability of keeping the decision about participation in home intravenous antibiotic therapy in the hands of the health team, the patient, and the family rather than in the hands of insurance ompanies; and (3) the need to recognize that savings associated with home care cannot be calculated simply by multiplying the difference between home and hospital care for one treatment event times the anticipated number of events.

Clinical studies should determine appropriate standards of care for home intravenous antibiotic therapy by looking at questions such as the following:

- 1. Should patients always begin parenteral antibiotics in a medical setting (and, if so, for how long) or is it acceptable to start therapy at home?
- 2. How often should a patient be followed during home intravenous antibiotic therapy and by which health care worker?
- 3. Which patients are suitable candidates for home intravenous antibiotic therapy?

PUBLICATIONS

Articles and Chapters

Davis SH, Mather FJ, Brown GF, Waring WW. Submitted for publication. Outpatient intravenous antibiotic therapy in patients with cystic fibrosis: A randomized multicenter study.

Abstracts

None to date.

Presentations

Mather FJ, Davis S, Brown GF, Davis PW, Waring WW. Recruitment experience in the home intravenous antibiotic trial. Presented at the 13th Annual Meeting of the Society for Clinical Trials, Philadelphia, PA, May 1992.

Mather FJ. Davis S, Brown GF, Davis PW, Waring WW. Patient charges/costs in the home intravenous antibiotic trials. Presented at the 13th Annual Meeting of the Society for Clinical Trials, Philadelphia, PA, May 1992.



64

TRACE METAL INTERACTIONS IN LEAD-EXPOSED CHILDREN

GRANTEE

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Costs*
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Year 1 Year 2 Year 3
† n/a n/a
† n/a n/a

Year 4 Year 5 n/a n/a

/a n/a n/a /a n/a n/a

SUMMARY

Statement of the Problem

This project addressed several problems related to the diagnosis and treatment of lead poisoning in children by conducting five separate but interrelated studies, each differing somewhat in design and methodology. At the time the study was undertaken, determination of the activated/non-activated ratio of erythrocytic porphobilinogen synthase (PBGS) activity had not been undertaken in children with blood lead concentrations less than 20 micrograms Pb/dL whole blood. Studies, primarily in Europe, had not determined this ratio, but suggested that the threshold for inhibition of PBGS lay at a lower level than 20 micrograms Pb/dL whole blood. We therefore enrolled children with blood lead concentrations as low as 5 micrograms Pb/dL whole blood in this particular study (Study A).

While there had been anecdotal information that CaNa₂EDTA would mobilize substantial amounts of zinc, there was no formal study of this problem and no study at all on the effect of CaNa₂EDTA on plasma zinc and copper. Study B was designed to address this question.

The principal investigator had approached the manufacturer of CaNa₂EDTA to determine if they would be interested in manufacturing a CaZnEDTA, inasmuch as there was experimental evidence that this would be much safer that CaNa₂EDTA and almost as effective as CaNa₂EDTA. The manufacturer demurred. It was suggested that oral supplements of zinc and copper during CaNa₂EDTA would be just as effective. Study C was designed to study this question using a dose run-up design initially.



49

^{*} Indirect included/† Not available at the time of publication.

There were publications on the effect of d-penicillamine in mobilizing lead, but those publications dealt with its use for five days only. Inasmuch as the standard protocol at the time in Baltimore was to give CaNa₂EDTA initially for five days and then to follow it with long-term oral d-penicillamine therapy, the question arose as to the effectiveness of this in promoting a diuresis of lead, zinc, and copper. Study D was designed to address this question.

Lastly, we were attempting to see whether we could identify biomarkers for the effect of CaNa₂EDTA on renal function. Study E addressed this question, as well as other ancillary studies.

Research Questions or Hypotheses

Study A, "Dose-Effect Relationship Between Blood Lead (PbB) and Erythrocytic Porphobilinogen Synthase (PBGS) Activity in Peripheral Blood," was conducted primarily to define more precisely the blood lead threshold for the earliest evidence of inhibition of PBGS activity by lead.

Study B, "Decorporation of Lead (Pb) Zinc (Zn) Copper (Cu) and Cadmium (Cd) during Calcium Disodium Ethylenediaminetetraacetate (CaNa2EDTA) treatment of Lead-Poisoned Children" was conducted in 20 children to determine the pattern of urinary loss of these metals under the influence of CaNa2EDTA and to provide estimates of the portion of the prechelation body lead burden available for chelation by CaNa2EDTA that is excreted during a standard five day course of treatment with this drug.

Study C, "Zinc Supplementation During CaNa¿EDTA Therapy: Dose Run-Up Study" This was an outgrowth of Study B and was initiated during the latter part of the project period to determine whether oral supplements of zinc (together with small amounts of copper) could minimize the dramatic decrease in plasma zinc that occurs during CaNa2EDTA therapy, without influencing the drug's effect in reducing blood lead concentration and altering the output of lead in urine during therapy.

Study D, "D-Penicillamine (PCA) in Chronic Lead Intoxication," was conducted to evaluate the effect of this drug on Pb, Zn, and Cu in blood and urine during long-term administration of PCA.

Study E included several small ancillary studies carried out in small numbers of children and in the laboratory in an attempt 1) to identify biological markers of the effect of CaNa₂EDTA on renal function, changes in the Pb, Zn and Cu content of subcentimeter segments of hair. This study also included an unsuccessful attempt to measure Zn quantitatively in circulating leukocytes as a possible measure of the potential effect of CaNa₂EDTA on intracellular zinc.

Study Design and Methods

Study A—Blood Lead-PBGS Relationship: The subject of this study included 91 children, 82 of whom were black. The majority of children ranged between 1 and 6 years of age. The overall median age was 44 months. Mean PBB was 36.9 ug/dl of whole blood. These children were drawn from three major sources: (1) Kennedy Institute Lead Clinic (Baltimore) for data in children with PbB greater than 25 ug Pb/dl of whole blood; (2) two primary health care centers on the northeast outskirts of Baltimore where lead



exposure is quite low (PbB less than 25 ug Pb/dl whole blood). In addition, twelve children attending the Pediatric Hematology Clinic of the Baltimore City Hospital were sampled to evaluate the influence primarily of sickle cell disease on the PBGS assay. PbB was determined in venous samples of blood by anodic stripping voltammetry (ASV). PBGS (formally known as ALAD) activity was determined by the European standardized method modified in this laboratory to incorporate reactivation of the enzyme with dithiothreitol (DTT). With this technique both activated and nonactivated PBGS activity were determined in duplicate 0.2 ml aliquots of blood while a fifth aliquot served as the blank. To prevent decay in enzyme activity, all samples were kept at -70°C from the moment of sampling until analysis. In the group of children studied, PbB ranged from 5-98 ug Pb/dl of whole blood.

Study B—Decorporation of Pb, Zn, Cu and Cd During CaNa, EDTA Treatment: This study was carried out in 20 children in the Pediatric Clinical Research Unit of the Johns Hopkins Hospital (JHH/PCRU) under the following protocol. Children with preadmission PbB of 40-70 ug Pb/dl whole blood, who were toilet trained and free of serious acute or chronic intercurrent disease, were eligible and were drawn from the Kennedy Institute's Lead Clinic held week:v on Wednesdays throughout the year. After informed written consent was obtained, children were admitted to JHH/PCRU. After a 3 day control period, they received CaNa₂EDTA in a dose of 1,000 mg/m2/24 hour for five days and remained in the hospital for two additional posttreatment control days. Twenty-four hour urine samples were collected throughout for measurement of Pb, Zn, Cu, and Cd. Serial blood samples were collected before, during and after treatment for PbB, plasma zinc, (ZnP) and plasma copper (CuP). Serial samples of blood were collected before, during and after treatment to monitor any changes in hepatic, renal or hematologic function during treatment. PbB was determined by ASV, while all other measurements were by atomic absorption spectrophotometry (AAS). Most of the children were transferred after therapy to the Kennedy Institute for continued inpatient chelation therapy with PCA, but were not studied during this phase of their treatment at Kennedy Institute. Data were analyzed by least squares regression analysis. Compartmental analysis was used to estimate the prechelation body PbB burden and the proportion of that burden excreted during-a five day course of CaNa, EDTA.

Study C—Zinc Supplementation During CaNa2EDTA Therapy (dose run-up study): Data in study B revealed substantial decorporation of zinc and a 38% decrease in plasma zinc during CaNa2EDTA therapy. In an attempt to determine whether oral supplementation with Zn, (and small amounts of Cu) could minimize or prevent the substantial drop in plasma Zn as a first step, a pilot dose run-up study was conducted. In succession groups of six children received first 5 mg Zn p.o., t.i.d., after meals, second 10 mg Zn p.o., t.i.d., after meals, and third 15 mg Zn p.o., t.i.d., after meals. Statistical analysis was by *t*-test for differences among the groups.

Study D—d-Penicillamine (PCA) in Chronic Lead Intoxication: This study was carried out in Mount Washington Pediatric Hospital (MWPH) in close collaboration with Paul Burgan, M.D., Ph.D. (Medical Director) in 30 children admitted directly from various clinics to MWPH. Informed written consent was obtained prior to enrollment and the protocol for the pretreatment control period and CaNa₂EDTA treatment was the same as



described under Study B. After three day rest periods, the children in this study received oral PCA in a single daily dose < 500 mg/m2/day. In the 17 nontoilet trained children, only data on PbB, ZnP, and CuP as well as the monitoring tests were obtained. In 12 children, useful 24 hour collections of urine were obtained before, during CaNa₂EDTA and according to protocol at weekly intervals during PCA therapy. All metal measurements were made in the Trace Metal Laboratory of the Kennedy Institute under this project by the methods listed under Study B.

Study E—Ancillary Studies: Strands of hair from children with serial PbB data before, during and after chelation therapy were forwarded to the Environmental Health Sciences Center at the University of Rochester for analysis by x-ray fluorescence using a custombuilt apparatus unique to that Center. Thirty-six serum samples obtained from five children before, during and after courses of CaNa₂EDTAand PCA were analyzed for ceruloplasmin and Cu in serum to determine whether CaNa₂EDTA or PCA would alter the relationship between these two measures of copper in serum. In the laboratory attempts were made to measure the content of Zn in circulating granulocytes and lymphocytes. However, we were never able to obtain consistent quantitative recovery of these leukocytes so that no clinical studies were carried out. N-acetylglucosaminidase-(NAG) activity is considered a sensitive but nonspecific indicator of renal cellular injury. Serial measurements were made in aliquots of 24 hour collections for the activity of NAG in urine by the procedure of Lockwood and Bosmann.

Study Sample and/or Population

With the exception of Studies A and D, all patients enrolled in these studies were drawn from the Kennedy Institute's Childhood Lead Clinic, which is held on a weekly basis and in which approximately 200 new patients per annum were seen at the time. The Clinic serves primarily an inner city black population, indeed, 90–95% are black (leaving about 5% white), being primarily equally divided by the sexes. 80% are Medical Assistance recipients; about 10–15% had no third party coverage at the time. The majority of the white patients had commercial third party coverage.

At the time, children were referred to this clinic by primary health care providers when blood lead concentrations exceeded 25–30 micrograms Pb/dL whole blood. The children in Studies B and C were recruited entirely from this clinic, and, after formal written consent was obtained, were admitted to the Pediatric Clinical Research Unit (PCRU) of the Johns Hopkins Hospital, where the studies were carried out.

For Study A, some of the children were drawn from the Kennedy Lead Clinic. It was, however, necessary to obtain additional subjects from a newly built "lead-free" high-rise public housing complex on the northeastern outskirts of the city. It was from this clinic that we were able to obtain children, again all black, with blood lead between 5 and 25 micrograms Pb/dL whole blood. It was known at the time that children with sick¹⁶ cell disease reacted differently in the PBGS assay, primarily because of the very young cells in the circulation. Ten additional children were recruited from the Pediatric Hematology Clinic of the Baltimore City Hospital. In all, in Study A, there were 91 children, 82 of whom were black. While the majority of children ranged between one and six years of age, the overall median age was 44 months, and the mean blood lead concentration was 36.9 micrograms Pb/dL whole blood.



52

38

Study D was carried out in collaboration with Paul Burgan, M.D., Ph.D., medical director of the Mount Washington Pediatric Hospital (MWPH). In all, 30 children admitted from various clinics directly to MWPH were recruited in the study. The population was essentially the same as that attending the Kennedy Institute. These children were enrolled primarily to obtained serial urinary metal output data while receiving oral d-pencillamine during their long stay at this institution, which varied generally from one to as much as nine months.

Study E was carried out in the populations of Studies B and C as ancillary studies while they were in the PCRU of the Johns Hopkins Hospital.

Findings

Study A—PbB-PBGS Relationship: The expected correlation between PbB and nonactivated PBGS activity (r=0.775) was found in this study. This is the method usually used, but with this method the PbB threshold for inhibition of PBGS cannot be precisely defined. When the activated/non-activated PBGS activity ratios were plotted versus PbB, correlation increased to r=0.913, equivalent to an R2 value of 0.883, indicating that PbB accounts for the major portion (83%) of the observed variation in the ratio (activated/non-activated PBGS activity). The estimated Pb concentration in blood for a ratio of 1, indicating no inhibition of PBGS by lead, was 5 ug Pb/dl of whole blood or lower. Use of the ratio largely compensated for variations in PBGS activity due in part to genetic polymorphism of this enzyme and age distribution in red cell population. Similarly, when individuals with sickle cell disease or betathalassemia were studied and the ratio used, the observed values for the ratios of PBGS activity in relation to PbB agree with those predicted from the regression equation fitted to data obtained from normal children. In such patients without use of the ratio, PbB could be seriously either under- or overestimated.

Study B—Decorporation of Pb. Zn. Cu, and Cd During CaNa₂EDTA Treatment: When CaNa2EDTA is given in the dose according to the protocol described above, the immediate post treatment PbB is on average 58% of the immediate pretreatment value, while Zn at the end of therapy is 62% of its pretreatment value and plasma Cu remains unchanged. Plasma Zn rebounds to normal within 60 hours after treatment while PbB rebounds by an average of 5 ug Pb/dl of whole blood after 4 days, but not after 60 hours. The output of Pb and Zn in urine is linear with the cumulative dose of CaNa EDTA. Compartmental analysis indicated that an average of 62% of the estimated prechelation body Pb burden available for chelation by CaNa₂EDTA is excreted during a 5 day course at the above dosage. Considerations of safety preclude the administration of CaNa EDTA for more than 5 consecutive days, despite the fact the more Pb would doubtless be excreted if it were safe to continue CaNa EDTA any longer. The data suggested that body Zn stores may be more labile in younger children than in older children. In this group of children the output of Pb in urine increased by about 10 fold, zinc output by about 15 fold, Cd output by about 2.8 fold. Urinary Cu loss was not significantly increased by CaNa₂EDTA. Within 12 hours after the last dose of CaNa₂EDTA urinary output of all metals returned to endogenous levels.

Study C—Zn Supplementation During CaNa₂EDTA Therapy (dose run-up study): Data from this pilot project, which was started toward the end of the project period and



completed later suggested that oral supplementation with Zn at a dose of 10 mg t.i.d., p.c. and Cu at a dose of 0.5 mg t.i.d., p.c. during CaNa₂EDTA therapy might ameliorate the drop in plasma Zn during CaNa₂EDTA therapy. Without supplementation plasma Zn averaged 62% of the pretreatment value after 5 days of treatment. With supplementation at this dose, plasma Zn was 75% of the pretreatment value at the end of therapy. However, the differences among the groups involving small numbers of patients (6 subjects per dose interval) were not statistically significant, but the trends were in the desired direction. To confirm the findings in this pilot study, a randomized trial would be necessary involving larger numbers of patients. In the absence of such a study, it would be prudent to administer such supplements during CaNa₂EDTA therapy particularly to iron deficient "milk babies" who are likely to be deficient not only in Fe but also in Zn and Cu, owing to the suboptimal levels of these metals in cow's milk.

Study D—d-Penicillamine (PCA) in Chronic Lead Intoxication: In this study carried out in 30 CaNa₂EDTA at MWPH, the data on the rate of decrease in PbB and plasma Zn during CaNa₂EDTA therapy in Study B were confirmed. In this group (Study D), mean pretreatment PbB was 53.73 ug Pb/dl whole blood and the immediate post-treatment value was 31.37 ug Pb/dl whole blood. Thereafter, on PCA therapy, PbB remained unchanged during the next three to 18 weeks that it was administered at MWPH. The data also showed that PCA, when administered following a 5-day course of CaNa, EDTA, is relatively ineffective in enhancing the urinary excretion of lead which is increased by a factor of two or slightly more while Zn is increased by almost threefold during PCA therapy. On the other hand, while CaNa EDTA has little effect on the urinary loss of Cu, PCA increased the urinary loss of copper by an average of 21-fold. Because CaNa₂EDTA and PCA have relatively high affinities for Zn and Cu, respectively, they are not ideal agents for the treatment of lead toxicity. A drug such as DMSA which has a relatively low affinity for essential metals in combination with a high affinity for nonessential metals such as Pb, As, and Hg, would appear to be preferable. Furthermore, it can be given orally. At present, DMSA is classified as an investigational drug by the FDA.

Study E-Ancillary Studies: Serial measurements of Pb, Zn and Cu in sub-centimeter segments of hair, when compared with serial measurements of these metals in blood, appear to offer no advantage over the blood measurements. Furthermore, the sharp changes which occur during chelation therapy were not found in the serial measurements on hair. Serial measurements of NAG activity in 24-hour urine collections revealed no changes in the loss of this indicator of renal cellular injury during five day courses of CaNa₂EDTA. The techniques for separating leukocytes available at the time of the start of this study were techniques developed by geneticists interested in cloning single cells but not in quantitative recovery of granulocytes and lymphocytes. While we were able to obtain good quantitative recoveries of granulocytes separated from lymphocytes in some samples in preliminary experiments in the laboratory, we were never able to obtain quantitative recoveries of these cell types consistently. Therefore, no clinical studies were carried out. However, such measurements remain of interest as they could provide data as to whether CaNa₂EDTA decorporates Zn from intracellular sites. In serial samples obtained from five children no evidence was obtained to indicate that the ratio of serum Cu to serum ceruloplasmin is altered during CaNa₂EDTA or PCA therapy.



Recommendations

In view of the recent findings of adverse effects of lead on neurodevelopment during fetal and early postnatal life, there is an urgent need for more sensitive indicators of lead toxicity that can be measured in critical populations such as young children. The currently, widely used FEP test as the primary screening test is of limited value at low levels of PbB and Pb toxicity. At the present time PbB measurements represent the only available option. Should methods be developed which would stabilize PBGS activity in capillary samples of blood during the time between sampling and analysis and if automated procedures could be developed in the laboratory for its measurement this might be an alternative; however, it is likely that research in this regard will have to take new directions. With regard to treatment, as stated above, more research into the development of safe and efficacious treatment protocols for the use of DMSA need to be developed. Studies in animals indicate that repeated courses are likely to be needed and certainly that 5-day courses are inadequate. That 5-day courses are inadequate has also been demonstrated in man as PbB rebounds and Pb is internally redistributed among the tissues. In rats after a period of time, there is no difference in the tissue contents of Pb between controls and animals treated with DMSA for 5 days. Safe and efficacious treatment protocols for DMSA need to be developed.

Publications

Articles and Chapters

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Thomas DJ Chisolm JJ Jr. 1986. Lead, zinc and copper decorporation during calcium disodium ethylenediamine tetraacetate treatment of lead poisoned children. *Journal of Pharmacology and Experimental Therapeutics* 239:829–835.

Abstracts

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Thomas DJ, Chisolm JJ Jr. 1986. Lead, zinc and copper decorporation during treatment of lead-poisoned children with calcium disodium ethylenediamine tetraacetate, (CaEDTA). *The Toxicologist* 48.

Thomas DJ, Chisolm JJ Jr. 1987. Toxic and essential metal loss during chelation therapy of lead poisoned children. The Proceedings of the Conference on Trace Elements in Man and Animals, Pacific Grove, CA, May/June, 1987.

Presentations

None to date.



COURSE OF RECOVERY FOR CLOSED HEAD TRAUMA IN ADOLESCENCE

GRANTEE

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PROIECT NUMBER

MCJ-240510

REPORT NUMBER

MCH/CCS-90/08

NTIS NUMBER

PB92-139054

PROJECT PERIOD

10/01/84-09/30/88

Costs*

Year 1 Year 2 Year 3

Year 5 Year 4

n/a

Awarded

92,464 88,327 no cost n/a

78,632

extension

Requested

96,359 91,473 79,306

no cost

extension

SUMMARY

Statement of the Problem

Closed head injury as a result of automobile and other accidents is a major cause of morbidity and mortality for adolescents. For example, 70 percent of the adolescents admitted for major trauma due to motor vehicle accidents at the University of Maryland Hospital sustain neurological injuries. Most of these are closed head injuries. This experience is similar to other trauma units around the United States. Closed head injuries hospitalize 432,000 individuals each year. As a result or these injuries, more than 75,000 Americans have long-term disability. Finally, there are more injuries and deaths per licensed driver among individuals 18 years of age than in any other age group.

Few studies have focused on the long-term effects of head injuries on adolescents. The studies that have been done suggest that recovery is age-related. These studies have only begun to define more readly recognizable patterns of persistent neurological lesions. The results show impaired intellectual functioning with short-term memory loss. There have been virtually no studies that focused on the interaction of the residual central nervous system deficit with respect to family and school. Impaired intellectual functioning should impact on family functioning, school performance, peer relationships, and behavior at school. We have observed that interactions with school personnel about



^{*} Indirect included

appropriate academic planning are frequently problematic for these patients and their families.

Research Questions or Hypotheses

The purpose of this study was to investigate the central nervous system deficits that occur in adolescents with closed head injuries and the resulting impaired intellectual functioning. This study addressed the following question: If closed head injury adversely effects cognitive performance, what is its time course?

Study Design and Methods

An initial neuropsychological battery of tests was administered to all subjects (adolescents with a closed head injury and a control group of uninjured adolescents) to assess various cognitive abilities. Subjects with a closed head injury received followup neuropsychological evaluation after recovery from posttraumatic amnesia. The tests were conducted at approximately 6, 12, and 13 months posttrauma. The uninjured control subjects received the neuropsychological evaluation upon enrolling in the project and 13 months later. The neuropsychological measures included the Wechsler Intelligence Scale for Children-Revised (or the Wechsler Intelligence Scale for Adults-Revised, when appropriate); the Selective Reminding Test (to assess retention, storage, and retrieval of variable information); the Trail Making Test; the Wisconsin Card Sorting Test; and the Control Oral Word Association Test.

Data were analyzed according to group identification (closed head injury versus control). The analyses used chi-square and *t* tests to determine whether there were differences between the groups' demographic characteristics. Multivariate analysis of variance (MANOVA) compared the closed head injury subjects with the control subjects. Neuropsychological performance initially and at 18 months followup was available for the controls. In addition, a MANOVA with repeated measures analyzed the psychometric data only for the closed head injury subjects. Detection of significant effects resulted in further analyses with post hoc paired comparisons.

Study Sample and/or Population

A total of 68 subjects participated in the study. All subjects were between the ages of 12 and 20 years and were enrolled in school. The first group included 33 adolescents admitted to a large university hospital after a motor vehicle accident. These young individuals met the criteria for a closed head injury. The second group was an uninjured control group recruited from a nearby school. This group comprised 35 subjects without a history of head trauma.

Findings

As predicted, the injured subjects scored lower than the control subjects on some of the neuropsychological measures. In general, their overall IQ was depressed. The adolescents with closed head injuries had lower full-scale IQ, verbal IQ, and performance IQ scores than their uninjured counterparts. As expected, at the initial evaluation, injured subjects' scores on tests assessing general fund of knowledge, attention to visual detail, perceptual and spatial skills, and visual motor speed and



accuracy were substantially below the scores of the uninjured controls. Control subjects made slight improvement on the block design and object assembly subtest over the 18 months. Adolescents with closed head injuries made strong gains on these measures of perceptual spatial ability. This suggests that the deficits were injury-related. Improvement occurred in visual detail, perceptual motor speed, and accuracy. Closed head injury subjects scored lower than the controls in vocabulary, numeric reasoning, common sense and social judgment, and reasoning and abstract thinking at any time during the study. Real gains by the head injured were not observed on the verbal subtest of the neuropsychological testing. Since the vocabulary subtesting is considered the best sign of premorbid and intellectual ability, this raises the chance of premorbid pathology. However, CAT scans and electroencephalography findings revealed more damage to the left hemisphere than to the right among the adolescents with closed head injuries. Thus, the observed verbal deficits would be consistent with the site of injury. Adolescents with closed head injuries also had deficits in their sequencing skills, visual scanning abilities, and cognitive flexibility measured by the trail making test. Testing revealed deficits in abstract thinking. It also appeared that most cognitive recovery occurs in the first 6 months following injury, but that some deficits take longer to recover.

Recommendations

These finding have important implications for rehabilitation and academic planning. These results suggest that the adolescent who has sustained a closed head injury will benefit most from cognitive training during the initial 6 months after the injury. Educators involved with adolescents should be aware of the cognitive changes that occur over the first 6 months to 1 year. Reevaluation for school placement two to four times during the first year after head injury is essential. Such reevaluation should be based on demonstrated improvement in the classroom and neuropsychological assessment. Even when improvement reaches the normal range in cognitive ability, recovery may not be complete. Functioning within the normal range may not reflect what is normal for that particular individual. As health professionals, patients, and parents plan for the period of cognitive recovery, these factors need to be considered in offering appropriate recommendations. These recommendations need to be based on neurophysiological testing, and performance at home and at school.

PUBLICATIONS

Articles and Chapters

Slater EJ. 1989. Does mild mean minor. Journal of Adolescent Health Care 10:237-40.

Slater EJ, Bassett SS. 1988. Adolescents with closed head injuries. *American Journal of Diseases of Children*. 142:1048–51.

Slater EJ, Kohr MA. 1989. Academic and intellectual functioning of adolescents with closed head injury. *Journal of Adolescent Research* 4(3):371–84.

Slater EJ, Rubenstein E. 1987. Family coping with trauma in adolescents. *Psychiatric Annals*. 17(12):786–94.



Slater EJ, VanWagoner SL. In preparation. Validity and utility of WAIS-R and WISC-R short forms with adolescents recovering from closed head injury.

Abstracts

None to date.

Presentations

None to date.



CHILD CARE ARRANGEMENTS AND ACUTE ILLNESSES IN PRESCHOOLERS

GRANTEE

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PROIECT PERIOD

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Costs*
Awarded
Requested

Year 1 Year 2 Year 3 Year 4
† † n/a n/a
† † n/a n/a

Year 5

n/a

n/a

SUMMARY

Statement of the Problem

Numerous studies have documented an association between child care attendance and a variety of acute illnesses in young children. Despite substantial epidemiologic evidence on transmission of infectious agents in child care settings, the risk of acute gastrointestinal or respiratory illness directly attributable to care has been difficult to delineate due to (1) an almost exclusive focus on center-based care to the exclusion of children who are cared for by their parents or in home-based settings, and (2) the reliance on small samples which constrain the investigator's ability to control for potentially confounding variables.

Research Questions or Hypotheses

The purpose of this study was to examine the risk of experiencing a respiratory or digestive condition for children who received care in their own homes, in someone else's home, or in a child care center.

Study Design and Methods

The source of the data for this study was the 1981 National Health Interview Survey and the 1981 Child Health Supplement. Three data files were used from the National Health Interview Survey along with the Child Health Supplement tape. These data files consisted of (1) personal records, which provided sociodemographic information about



^{*} Indirect included/† Not available at the time of publication.

the child's household and family members; (2) conditions records, which indexed information on acute and chronic conditions reported for each member of the household; and (3) doctor visit records, which provided information on each physician contact for all acute digestive and respiratory conditions experienced by the preschooler in a 2-week period.

Child care arrangements were defined based on the site where child care was provided. Four categories were used: No care (meaning parental care only), care given in the child's own home, care given in someone else's home, and care provided in a center/nursery school. In addition, the number of hours spent in all types of child care was calculated for each child as an indicator of illness exposure.

Acute respiratory and acute gastrointestinal conditions were defined using the ninth revision of the International Classification of Disease (ICD-9). Other variables considered as possible correlates of acute respiratory or acute gastrointestinal illness were: Age, race, and gender of the child; family structure; socioeconomic status; number of children in household; presence of a school-age child in household; a measure of crowding (regardless of whether the child shares a sleeping room with one or more family members); family income; region of the country where the child lives; and season of the year when interview took place.

Since the data from the Child Health Supplement and the National Health Interview Survey were collected using a multistage cluster sample design, specialized software was used to adjust for standard errors of the estimates. Software was leased from the Research Triangle Institute. SESUDANN was used to calculate rates, and RTILOGIT was used for the multivariate logistic analyses.

Study Sample and/or Population

The study sample was restricted to all children ages 71 months and younger who had not yet attended first grade at the time of the survey, and whose biological mother, biological father, stepmother, or adoptive mother served as the respondent for the Child Health Supplement. In total, 4,845 children were included; 2,751 ranged in age from birth to 35 months and 2,094 ranged in age from 36 to 71 months. There were 298 primary sampling units which represented all primary sampling units and strata included in the 1981 National Health Interview Survey.

Findings

The overall prevalence of a reported acute respiratory condition for the 2-week period was 11 percent for children under age 3 and 8 percent for children ages 3–5 years. Controlling for the effects of other variables, the risk of reported ear infections in children who attended child care centers was two times greater than for children in other care arrangements. In addition to center care exposure, risk of illness was increased among nonwhite children, children who lived in less crowded households, and children whose parents were interviewed in the winter and spring months.

Analyses of the prevalence of an acute gastrointestinal condition revealed that 1 percent of the sample reported the condition in the 2-week period. Percentages were higher for nonwhite children, children under age 3, children living in low-income



61

families, children living in crowded households, and those who reported center care attendance. Among children under 3 years of age, the risk for an acute gastrointestinal illness was three and one-half times greater for children in center care compared with children in all other care arrangements.

Comparisons of children with a bed disability day or a restricted activity day by type of child care yielded no significant differences. Findings from the multivariate analyses of the likelihood of a restricted activity day or a bed disability day indicated that family income, gender, and socioeconomic status were the only significant factors.

Recommendations

Results from this study indicate that center care poses some health risks for children under 3 years of age. At the same time, students have shown that the health risks associated with acute gastrointestinal illness can be effectively reduced through surveillance, training, and monitoring of hygienic practices of child care workers. State agencies should continue to establish handwashing regulations for group care settings and aggressively pursue their implementation.

PUBLICATIONS

Articles and Chapters

Alexander C, Zinzeleta E, MacKenzie E, Vernon A, Markowitz R. 1990. Acute gastrointestinal illness and child care arrangements. *American Journal of Epidemiology* 131:124–132.

Abstracts

None to Date.

Presentations

Alexander C, Zinzeleta E, MacKenzie E, Vernon A, Markowitz R. Day care and acute illnesses in preschoolers. Presented at the 115th Annual Meeting of the American Public Health Association, New Orleans, LA, October 1987.



IMPACTS OF FINANCING MATERNITY CARE FOR THE POOR AND UNINSURED

GRANTEE

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PROIECT NUMBER

MCJ-240545

REPORT NUMBER

MCH/CCS-89/12

NTIS NUMBER

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PROJECT PERIOD

Awarded

Requested

10/01/86-09/30/88

Costs*

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 124,265
 150,202
 n/a
 n/a
 n/a

 140,772
 155,178
 n/a
 n/a
 n/a

SUMMARY

Statement of the Problem

The Institute of Medicine report (1985) on preventing low birthweight identified barriers to improving the birthweight distribution. The report emphasized problems of financial and geographic access to high quality prenatal care. Although there is some uncertainty concerning the exact contribution of adequate prenatal care to past reductions in low birthweight rates (prior to 1979), there is a growing consensus that expanding access to prenatal care is a key component in any strategy to shift the birthweight distribution upward.

Following a decade (1969–79) in which the percentage of women receiving prenatal care in their first trimester of pregnancy rose steadily, the years since 1979 have shown no gains in timely initiation of prenatal care. The percentage of women initiating prenatal care in the first trimester was the same in 1983 as in 1979. Trends in the use of prenatal care during the early 1980s display important departures from the gains of the 1970s.

National trends in health care funding for low-income populations may be contributing to restricted access to prenatal care. According to recent estimates, the number of Americans without insurance is growing. In 1979, approximately 14.6 percent of the population (excluding the elderly population) was uninsured, compared to 17.5 percent in 1986. The growth rate in the number of uninsured is even higher for those with incomes less than 200 percent of the Federal poverty level.



^{*} Indirect included

Research Questions or Hypotheses

The goal of this study was to develop an econometric model of factors that influence access to prenatal care for low-income women and the subsequent effects on rates of low birthweight births. The most relevant findings are those that establish empirical links between public financing of prenatal care, use of prenatal care, and birthweight outcomes. The study has provided estimates of these linkages and some simple projections of the impact of key policy changes currently under way.

The study examined the manner in which a number of specific types of resources and public policy actions affect the rate of low birthweight and very low birthweight births. Specifically, we have been concerned with the direct effects of the use of prenatal care, abortion services, and cigarettes on rates of low birthweight births. We also focused our model on the indirect effects on birthweight outcomes of Medicaid program structures and the availability of prenatal care and abortion providers.

Study Design and Methods

The empirical analysis used the county as the unit of observation. The study design was a pooled time series cross-sectional study for the years 1975–84. The empirical strategy consisted of estimating a series of regression models that traced the structural relationships outlined in the theoretical model. Separate regressions are estimated for black and white birthweight outcomes and also by three age groups (less than 20 years, 20–34 years, and 35 years and older). Separate race- and age-specific regressions were used because race and age are thought to interact with a variety of other explanatory variables. For instance, the low birthweight rate for blacks is roughly twice that for whites. Race and age are also correlated with use of prenatal care, abortion services, and other explanatory variables. Thus, the estimation of age- and race-specific regressions also reduces collinearity problems.

Study Sample and/or Population

The study population consisted of all counties in the United States with populations of 10,000 or more whites, or 5,000 or more blacks (based on the 1980 census). The age-and race-specific regressions were estimated for samples of counties with at least 5,000 blacks or 10,000 whites. The study combined data from birth records for 2 years for each county data point to reduce problems of random fluctuations in rates of low birthweight births. Thus, we estimated our models for counties for even-numbered years 1976–84. Data from the birth records are combined for the following 2-year pairs: 1975–76, 1977–78, 1979–80, 1981–82, and 1983–84. The result is a panel of 2,192 counties that met the white population criterion and 686 counties that met the black criterion.

Additional criteria were applied in constructing the data base used for analysis. Counties that reported more than 30 percent of observations missing from items on individual birth records were eliminated from the analysis file. Arizona was eliminated from the analysis file since it did not have a Medicaid program during the study period. These sample selection criteria led to reductions in the final sample of counties included in the study: The white sample comprised 2,137 counties, and the black sample comprised 660 counties. These counties are included in panels that consist of five 2-year pairs.



Findings

Our empirical models show that for adolescents and women 35 years and older, prenatal care has a significantly more pronounced effect on whites than on blacks. For those in the 20–34 year age group, prenatal care has a significantly stronger effect on low birthweight rates for black women compared to whites. The most significant impact of prenatal care on rates of low birthweight births is for adolescents of both races.

Differences in the impact of prenatal care by age conform to our expectations. Because adolescent women who become pregnant often face difficult circumstances such as low income, single parenthood, and family disruption, receiving medical attention might be particularly beneficial. Also, one might expect the impact of additional visits to be greater because the average level of visits for an adolescent is relatively low (8.7 visits for white adolescents compared to 10.7 visits for women ages 20–34 years).

In general, increasing access to prenatal care for both races will lead to significant reductions in the low birthweight rate. For example, increasing the average number of prenatal visits for black adolescents by approximately 2.5 (which would bring the average to about 11 visits) would reduce the low birthweight rate by 1 percentage point. This implies a decline in the low birthweight rate from about 14 percent to 13 percent. With respect to initiating prenatal care in the first trimester, the impact is much more modest: An increase of 10 percentage points in early initiation would lead to a 0.1 percentage point decline in the low birthweight rate (from 14 percent to 13.9 percent).

For black women ages 20-34, an increase in prenatal visits from a mean of 9 to 11 would result in a 0.44 percentage point decrease in the low birthweight rate (from 12.08 percent to 11.64 percent). An increase of 10 percentage points in women initiating care in the first trimester would result in a 1.7 percent decline in the low birthweight rate (from 12.08 percent to 10.38 percent).

Among white adolescents, an increase in prenatal care visits from a mean of 9.90 to 11 visits would reduce the low birthweight rate by 1.82 percentage points (from 7.5 percent to 5.7 percent). Increasing the percentage of adolescents initiating prenatal care in the first trimester by 10 percentage points (from 60 percent to 70 percent) would reduce the low birthweight rate from 7.5 percent to 5.5 percent. Both of these represent significant changes. In addition, increased access will also be associated with reduced very low birthweight rates for white women.

Recommendations

The racial differences we have found are somewhat surprising. We would have expected the low birthweight rate of black women to be more sensitive to increases in prenatal care. While this was true for the majority of births (among women ages 20–34), it was not true for those who have often been considered at higher risk (adolescents and women over age 35). Prenatal care had a larger impact for the youngest and oldest age categories. While we do not have a rigorous explanation for the racial differences, data from the 1982 National Survey of Family Growth provide a clue. Approximately 53 percent of black women received their prenatal care from a clinic, while 40 percent obtained care from a private physician or group practice. In comparison, 30 percent of white women received care in a clinic and 63 percent received care from a private



physician or group. This suggests that it may be important to learn more about the process of care within different organizational settings. It is important to note that little appears to be known about the process or content of prenatal care. Such knowledge will expand our ability to interpret results such as those reported above.

This study relied on aggregate county data. While there is much policy-relevant information to be gleaned from these data, more effort at analysis of data on individuals would clearly advance our understanding of behavioral responses to economic factors. The studies to date using individual data have either been limited with respect to the variation in economic conditions or have relied on nonrepresentative samples. National data on individuals giving birth which includes detailed information on their health-related behavior and economic situation would contribute greatly to improving our knowledge in this area.

PUBLICATIONS

Articles and Chapters

None to date.

Abstracts

None to date.

Presentations

None to date.



THE EARLY INTERVENTION COLLABORATIVE STUDY: PHASE ONE

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Project Number MCJ-250533

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PROJECT PERIOD 01/01/86-06/30/89

Costs* Year 4 Year 5 Year 2 Year 3 Year 1 331,727 115.124 n/a Awarded 257,253 27,811 257,253 339,076 243,046 123,548 n/a Requested

SUMMARY

Statement of the Problem

The central research problems currently facing the field of early childhood intervention are both theoretical and pragmatic. On a conceptual level, many important questions remain unanswered concerning variations in development and the stability of individual differences among children with disabilities and their families. From the practical perspective of service delivery, matching individualized intervention strategies to the specific needs of a diverse population of children and families, and measuring impacts over time, are critical for the translation of policy objectives into effective programs. One important challenge is the need to integrate basic developmental and policy-related research in order to respond to these complex issues.

Research Questions or Hypotheses

The Early Intervention Collaborative Study was established to address two interrelated goals: (1) Enhance our understanding of variations in development by investigating predictors of competence in young children with disabilities, and the adaptation within their families; and (2) improve our ability to match service programs to their recipients by analyzing the mediating influences of family ecology and early intervention services on children and families. Phase 1 of the study, which focused on the first year of early intervention program participation, investigated three areas of inquiry: (1) The relative merits of categorizing children by their type of disability in



^{*} Indirect included

comparison to the level of severity of their psychomotor impairment as a means of predicting change in child and family outcomes; (2) the hypothesized relations among selected child, family status, and mediating variables and changes in outcomes; and (3) the extent to which specific types and characteristics of early intervention services contribute to the explained variance in child development and family adaptation.

Study Design and Methods

This study was a nonexperimental, longitudinal investigation of the development of 190 infants with disabilities and their families. Data were collected through home visits conducted within 6 weeks of entry into an early intervention program (T1) and again 12 months later (T2). Each home visit was conducted by two members of the research staff, who remained blind to the study's hypotheses. During the T1 visit, one staff member administered a structured evaluation of the child, which included a standardized developmental assessment, a free play observation, and a rating of mother-infant interaction. The second staff member conducted an interview with the mother, which included an evaluation of the child's adaptive behavior and caretaking needs, as well as a review of services received in addition to those provided in the early intervention program. Two identical packets of self-administered questionnaires were left to be completed independently by the child's mother and father. Questionnaires included scales on parenting stress, social support, family functioning, locus of control, and impact of a child with a disability on family life. During the interval from T1 to T2, standardized information on child and parent services received through the early intervention programs was collected monthly from service providers (who were blind to the study hypotheses and measures). The T2 home visit consisted of a repeat administration of the child assessments, a detailed interview with the mother, and administration of identical questionnaires to those completed by each parent at T1, with several additional measures of the perceived benefits of early intervention. After completion of the T2 visit, a set of questionnaires on service impacts was sent to the early intervention case manager.

The statistical analyses used to examine the study data involved standard nonparametric and parametric bivariate and multivariate procedures. The analysis of change in children and families between T1 and T2 was based on residual scores (standardized to a mean of zero and a standard deviation of one). Standard parametric statistical procedures were employed to test for either significant differences in the residual scores by group membership or the percentage of variance accounted for in the residuals by the independent variables.

Study Sample and/or Population

The study sample comprises 190 children with disabilities and their families, who were recruited between November 1985 and December 1987 from 29 community-based early intervention programs in Massachusetts and New Hampshire at the time of referral for service. Eligibility was determined by the child's presenting developmental problem, as defined by each of three groups: Children with Down syndrome (N = 54); children with motor impairment, defined by abnormality in muscle tone with delayed or atypical motor development (N = 77); and children with developmental delays of uncertain



68

etiology (*N* = 59). Mean age at study entry was 10.6 months. The ethnic composition of the sample was 88.8 percent white, 4.7 percent Latino, 2.3 percent black, and 4.2 percent mixed racial or other ethnic origin. Fifty-six percent of the children were male. Despite their racial homogeneity, sample families reflected a fair degree of socioeconomic diversity. The mean education level for both mothers and fathers was 13.8 years. Nine percent of the mothers did not complete high school; 14 percent had more than four years of college. At the time of study entry, the median family income was between \$20,000 and \$25,000 per year. Nineteen percent of the sample had an annual income of less than \$10,000; 36 percent earned more than \$30,000 per year. The demographic characteristics of the study sample mirrored those of the early intervention population in Massachusetts and New Hampshire. Sample membership was restricted to English-speaking persons, because translations of the core parent questionnaires were unavailable.

Findings

The magnitude of change in the study children over the 12-month period was comparable to that reported for previously studied infants receiving services. Within the sample, developmental changes in the children were influenced to some extent by their premature status and health characteristics, but the single most significant predictor of differential change across all of the child-dependent measures was the severity of the child's psychomotor impairment at the time of entry into the study. Although socioeconomic status and quality of home environment were significant and consistent correlates of many key family variables, they did not relate significantly to any of the child outcomes, except for the responsiveness of infants to their mothers at T2. This finding parallels the pattern seen in normally developing children, for whom social class influences on development typically do not appear until after 2 years of age.

In general, parents demonstrated relatively adaptive behavior at program entry and maintained a stable level of adaptation over the 12-month period of study. The one exception was mother-child interaction, with persistently low scores, and significantly lower scores for mothers in the low socioeconomic status group. For all family measures, family and parent characteristics were better predictors of change than were specific attributes of the children. The precipitants and dimensions of parenting stress differed significantly for mothers and fathers: Paternal stress focused largely on issues related to attachment to the child, whereas maternal stress focused more on the personal impacts of parenting. Fathers of children with Down syndrome appeared to be more vulnerable than their wives and other fathers.

Three subgroups within the sample appeared to be at greatest risk for less positive outcomes. Children with severe psychomotor impairment demonstrated significantly slower developmental growth than children with mild or moderate disability, and their families experienced significantly greater negative impacts over time. Children with motor impairment demonstrated relative lags in social development compared to other children, and their mothers appeared to be more burdened by their care and reported less increase in helpful social support than did mothers of children with Down syndrome or developmental delays. Children with cardiac or seizure disorders also showed more adverse impacts on child and family adaptation.



Although each family in the study sample was enrolled in an early intervention program for 1 full year, there was considerable variability in the amount of actual services received, and slightly more than half of the families received additional services from other sources. Early intervention services that provided opportunities for parents to interact with other families were associated with greater positive changes in maternal social support. In contrast, services that were individualized and were provided predominantly through a single professional discipline were associated with greater gains in child development and decreased maternal stress. Home visits were regarded most favorably by families, and more hours of home visiting were associated with greater decreases in parenting stress. Participation in a parent support group, which occurred less often for families of lower socioeconomic status, was correlated with maternal reports of large, and more helpful social support networks. On the other hand, parents rated support groups as relatively less helpful than other program components, and more hours of support group attendance correlated with maternal reports of increasing personal and social/familial strain.

Mothers, fathers, and service providers were unanimous in their impressions that early intervention services during the first year were most beneficial for the child and mother (in that order) and of relatively less benefit for the family as a whole or for fathers as individuals. Yet, parents rated early intervention relatively more helpful when they attributed higher benefits to themselves personally or to the family as a whole. Although no social class differences were found on overall ratings of program helpfulness, mothers in the low socioeconomic status group reported relatively greater child benefits in behavior, while mothers in the high socioeconomic status group attributed relatively greater benefits in motor skills. With respect to family effects, mothers in the high socioeconomic status group attributed relatively higher benefits in learning specific intervention techniques, while mothers in the low socioeconomic status group reported relatively higher benefits in learning how to be a better advocate for their child.

Recommendations

The considerable variability found in service intensity raises important questions about how decisions are made in allocating program resources. Although consistent patterns in the data indicated particular vulnerability for mothers of lower socioeconomic status and for parents of children with motor impairment, the distribution of service hours appeared to have been driven largely by the level of severity of the child's psychomotor impairment. These findings suggest the need for a systematic examination of the criteria employed to determine priorities for the use of scarce resources.

The observed correlation between individualized services and greater gains in child development, in contrast to the association between group services and increased maternal social support, suggests that flexible models of service are needed to address both objectives. The potential benefits and drawbacks to parent support group participation also demand careful scrutiny. And finally, differences in adaptation demonstrated by mothers and fathers highlight the importance of considering the strengths and needs of the entire family in the process of program design.



The increasing involvement of outside therapeutic and support services during the first year of a family's participation in an early intervention program raises questions about the extent to which early intervention programs have adequate resources to accomplish the mandated coordination of diverse services. Our findings indicate that the "whole" service system must be defined precisely before it can be studied effectively and modified rationally.

The agenda for further research is extensive. The impact of socioeconomic status and other family variables on the development of children and families as they progress beyond the sensorimotor period deserves considerable empirical attention. The nature and correlates of mother-child interaction, its change over time, and its influence on both child competence and parent adaptation also require careful study. Finally, our finding that the predictors of change in children and families over 1 year are often different from the correlates of child or family status measured cross-sectionally underlines the critical need for prospective investigation of child development, family adaptation, and service impacts beyond the infant-toddler period.

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88



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76

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INFANTS OF DEPRESSED ADOLESCENT MOTHERS

GRANTEE Boston City Hospital

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PROJECT NUMBER MCJ-250559

REPORT NUMBER MCH/CCS-90/09

NTIS NUMBER PB92-139047

PROJECT PERIOD 11/01/87–10/31/90

Costs* Year 4 Year 5 Year 1 Year 2 Year 3 Awarded 79,550 80,673 4,929 n/a n/a Requested 79,550 80,673 18.642 n/an/a

SUMMARY

Statement of the Problem

Childbirth during adolescence is a major concern to clinicians and public officials because these births are so often associated with increased developmental, social, and medical hazards for both the mother and child. Despite these hazards, few investigators have identified potential mechanisms that may explain why parenthood during adolescence has such adverse effects on infants.

Recently, the striking similarity in the developmental and behavioral outcomes of the infants of adolescent mothers and the infants of depressed mothers was described. Cognitive development among both sets of infants and the interactional styles of the mothers are similar.

Research Questions or Hypotheses

The purpose of this research was to determine the prevalence of depression among adolescent mothers and to determine whether infants of depressed adolescent mothers have poorer outcomes than infants of nondepressed adolescent mothers.

Study Design and Methods

Adolescent mothers who met the study's eligibility requirements were consecutively recruited as they registered for prenatal care at Boston City Hospital. Mothers were requested to bring their infants to the 12-month interview so that these infants could undergo detailed anthropometric evaluation and testing, using the Bayley Scales of Infant Development and the Infant Behavior Record.



^{*} Indirect included

The mothers underwent a detailed semistructured interview at the time they registered for prenatal care, within 72 hours following the birth of their infant, and at 6 and 12 months postpartum. Demographic data and information were solicited about depression, social support, life stresses, drug use, infant temperament, and the number of injuries and hospitalizations. In addition, the mothers furnished urine for assay of metabolites of marijuana and cocaine at all encounters.

Depression was measured using the Center for Epidemiologic Studies Depression Scale (CES-D). This 20-item Likert scale is scored between 0 and 60, with scores greater than 16 consistent with depression. The measure is considered both reliable and valid in the adolescent population. Because of the potentially high prevalence of depression in this group, depression was also coded as the top 25th percentile score at all encounters.

Study Sample and/or Population

Adolescent women who registered for prenatal care at Boston City Hospital were eligible for this study if, at time of delivery, they consented to be interviewed at 6 and 12 months postpartum, spoke English or Spanish, and had no major mental illness, and if their infant was full-term and spent less than 24 hours in the newborn intensive care unit.

The study sample consisted of 127 women enrolled at the time of the birth of their child; 97 women (76.4 percent) completed the 12-month postpartum interview and brought their child to that encounter for anthropometric and cognitive assessment. The mothers were predominantly young (90.4 percent were under age 18), poorly educated (19.1 percent completed high school or college), minority (73.4 percent were black), and poor (76 percent had monthly income under \$1,000, and 56 percent were recipients of Aid to Families with Dependent Children). All of the infants were full-term and well at the time of discharge from the hospital, with a mean birthweight of 3,159 grams (±490) and Apgar scores at 5 minutes ranging between 7 and 10, with a mean of 8.8 and a median of 9.0.

The mothers who did not complete the study (N = 30) were similar to those who did, with regard to maternal age, ethnicity, income, marital status, and depression measured at both 6 and 12 months postpartum.

Findings

Depression was common among these adolescent mothers. The mean score on the CES-D at 6 months was 14.9 (\pm 9.3), with 36 of 83 mothers (43.4 percent) having scores \geq 16. At the 12-month interview, the mean score was 14.2 (\pm 8.2), with 38 of 97 mothers (39.2 percent) having scores \geq 16. Overall, 26 of 90 women (28.9 percent) reported symptoms consistent with depression at either 6 or 12 months postpartum, 24 of 90 (26.7 percent) reported symptoms at both 6 and 12 months postpartum, and 40 of 90 (44.4 percent) reported no symptoms of depression at either encounter. Eighteen of 88 mothers (20.5 percent) were in the top 25th percentile at either 6 or 12 months, and 15 were in the top 25th percentile at both encounters.

No relationship was found between maternal depression at 6 months and/or 12 months (scored as either ≥16 or top 25th percentile) and either the Mental Scale or Motor Scale of the Bayley Scales of Infant Development (scored as either a continuous



variable or less than two standard deviations below the mean). For example, infants of mothers who were depressed at both 6 and 12 months postpartum had Mental Scale scores of 101.1 (\pm 11.3) compared to the scores of infants whose mothers were depressed at either visit (101.4, \pm 11.6) or not depressed (100.7, \pm 11.6, p=.96). Scores on the Motor Scale for the same three groups were 101.8, 102.5, and 104.0, respectively (p=.76).

Despite the lack of a univariate relationship between depression and scores on the Bayley Scales of Infant Development, a multiple regression analysis was conducted to control for confounding variables. Variables entered included depression, ethnicity, child's age at time of testing, maternal grandmother as primary provider in either the first or second 6 months of life, and total social support. The maternal grandmother as provider in the first 6 months was found to be significantly related to the mental score (p=.04). Infants raised by their maternal grandmother scored 8.3 points higher than infants raised by their mother.

Prior to the analysis, the principal and co-principal investigators categorized the 30 items on the Infant Behavior Record as being either suspect or not suspect with regard to positive mother-infant interaction. This type of analysis is similar to the one used by both Methany and Lozoff. Depression among adolescent mothers was not found to relate to total suspect scores on the Infant Behavior Record.

No relationship was found between depression and either weight or length at 1 year. Infants whose mothers were depressed at 1 year had similar weights (9.9 vs 9.9 kilograms, p=.98) and lengths (75.1 vs. 76.0 centimeters, p=.27) compared to infants whose mothers were not depressed. However, a relationship was found between maternal depression and infant head circumference at 1 year. Infants whose mothers were depressed at 1 year had head circumferences of 45.09 centimeters; infants whose mothers were not depressed at 1 year had head circumferences of 45.80 centimeters (p=.019). The difference in head circumference was similar when depression was coded as the top 25th percentile at 1 year (44.91 vs. 45.75 centimeters, p=.006).

Since the quality of the mother-infant interaction is difficult to determine during cognitive assessment, a subset of the sample (N=35) was visited at home shortly after the 12-month interview and assessed using the Nursing Child Assessment Training-Teaching Scale (NCATS) and the Home Observation for Measurement of the Environment (HOME). The majority of this set of mothers were black (68.5 percent), and otherwise similar to the entire sample. In this subset, mothers who were depressed at 6 months had a significantly lower NCATS score than mothers who were not depressed (45 vs. 50, p <.001). This difference remained after controlling for maternal age, income, ethnicity, use of drugs, and social support. Depression at 1 year was not related to either NCATS or HOME scores.

Recommendations

Depression was a common and persistent symptom among our sample of adolescent mothers, and, in a subset of the sample, it adversely affected the mother-infant interaction. In addition, the infants of depressed mothers had smaller head circumferences than nondepressed mothers. We did not find that the depression among



these women affected the cognitive development of their children, as measured by the Bayley Scales of Infant Development and Infant Behavior Record, at 1 year of age.

Our finding that depression may adversely influence how adolescent mothers interact with children is consistent with the literature on depressed mothers. Depressed mothers are known to talk to and look at their infants less frequently than nondepressed mothers. This behavior among adolescent mothers would influence how they would be scored on the NCATS.

Our finding that infants raised by their maternal grandmothers early in life did better than infants raised by their adolescent mothers on the Mental Scale of the Bayley Scales of Infant Development is consistent with many of our clinical observations. Many of these adolescent mothers have few parenting skills, while, in many cases, their mothers have raised other children and are skilled care providers. Since this was not a main hypothesis of the study, further research is needed on the intergenerational effects of child rearing.

No relationship between cognitive development and depression was found. This may have occurred for several reasons. First, depression may not adversely influence cognitive development among infants of adolescent mothers. Many of these infants were cared for by individuals other than their mother and this may have "hidden" the effect of depression. Second, adverse infant effects have been reported among mothers with diagnosable depression; this study measured symptoms consistent with depression, rather than diagnosable depression. Third, this study may not have followed the infants long enough to find an effect on cognitive development. The lower scores on the NCATS suggest that infants of depressed adolescent mothers may eventually have poorer intellectual development, depending upon the persistence of the mother's depression.

We conclude that depression is common among adolescent mothers, and it does appear to affect the quality of the mother-infant interaction, but not the intellectual development of the infant. Health care providers should be alert to signs or symptoms of depression among adolescent mothers, and, when symptoms are found, should observe the mother-infant interaction.

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Articles and Chapters

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Abstracts

None to date.

Presentations

None to date.



STATE CENSUS OF TECHNOLOGY-DEPENDENT CHILDREN

GRANTEE

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PROJECT NUMBER

MCJ-250590

REPORT NUMBER

MCH/CCS-91/10

NTIS NUMBER

PB92-161132

PROIECT PERIOD

Awarded

Requested

10/01/89-09/30/91

Costs*

Year 1 Year 2 Year 3 Year 4 Year 5 136,609 165,815 n/a n/a n/a 156,699 144,560 n/a n/a n/a

SUMMARY

Statement of the Problem

Advances in medical and surgical technology in the last 20 years, as well as new material development, miniaturization, and recognition that clean techniques can often replace sterile procedures, have led to a new reliance by physicians and surgeons on long-term technologic care for patients. These new practices have brought both new opportunities and new challenges. On the one hand, the new technologies have enhanced the life span of many patients and increased their chances to lead more functional lives. On the other, there have been greatly increased needs for long-term nursing, rehabilitation, and support services for this population of individuals who are dependent on medical technology and have complex medical needs.

In order to plan effective strategies for providing the services needed by children assisted by medical technology, it is essential to have a grasp of the size and configuration of the population to be served. In 1987, our research group (Project School Care) carried out a project to delineate the characteristics of the population of children in Massachusetts who were assisted by medical technology. This gave a one-time, cross-sectional look at the population, but did not give any appreciation of whether the population was increasing in size, nor the rate of increase (if any).

The purpose of the current study was to obtain a second data point in a similar manner to the data obtained in 1987, in order to assess longitudinal trends in the prevalence of technology dependence among children. By obtaining a comparable data set, questions regarding the size of the population, background characteristics, and parameters of medical technology use can be explored. Thus, we can estimate resource



86

^{*} Indirect included

needs in communities, as well as some early delineations of trends. We recognize that having one additional data point gives only the direction of the movement, not the magnitude, but we feel this is important to document.

Research Questions or Hypotheses

This study had four specific aims:

- 1. Estimate the number of children in Massachusetts depending on medical technology as of March 1990;
- 2. Estimate trends in the size of the medically dependent population by comparing data collected in the original 1987 study with data collected in 1990;
- 3. Use 1990 census data to estimate the prevalence of medical dependence by age; and
- 4. Determine the extent to which children depending on medical technology live and attend school in the community.

Study Design and Methods

The study was a 1-month point prevalence census of all children depending on medical technology in Massachusetts in March 1990. The original census instrument was developed in 1986 and used in March 1987. In order to compare data from 1987 to 1990, the same census instrument (with only modest modifications) and the same study methods were used.

All pediatric, nursing, and educational providers likely to have contact with children assisted by medical technology were alerted to the census effort by mailing. This included the medical and nursing directors of all hospitals with pediatric beds, nursing homes, pediatricians, Department of Public Health case managers, school nursing and special education directors, and directors of programs such as early intervention, multidistrict collaborative organizations, and the Massachusetts Association of 766 Approved Private Schools (MAAPS). The providers completed an individual census form on each child known to them.

We hoped there would be redundancy in responses on children in the census so that we could estimate a standard error of response and be assured of the reliability of our data gathering effort. As a result, we made sure to ask for census information from all service sectors.

Once the data were available, they were coded and entered into the computer, and a sorting procedure was used to look for duplicate cases based on background characteristics (initials, age, gender, zip code). From this sorting procedure, unique data sets were derived, representing unique individuals. In the case of multiple census responses, to increase reliability of information, algorithms were used to prioritize educational responses from education personnel and medical information from medical informants.

Study Sample and/or Population

The study was designed to determine the number of children in Massachusetts in 1987 and 1990 who depend daily on medical technology, including tracheostomy,



respirators, oxygen, suctioning, nasogastric tubes, gastrostomies, jejunostomies, ileostomies, colostomies, urostomies, clean intermittent catheterization, intravenous lines or devices, and dialysis. Since the goal of the study was to describe a sample of children chronically dependent on medical technology, the sample was limited to children ages 3 months to 18 years, in order not to bias the sample with neonatal intensive care unit residents who may be temporarily technology dependent. All children were residents of Massachusetts.

Findings

From the 1987 to the 1990 census, there had been a clear increase in the number of children meeting criteria of medical dependency. Overall, the increase was from 1,095 children meeting our criteria for medical technology dependency in 1987 to 1,576 children in 1990, a 44 percent increase. Because our estimated error around this number is less than it was in 1987, we believe this estimate is quite reliable and does not simply represent better ascertainment of subjects.

Within the overall group, the increases in technologies were not uniform. In fact, some technologies did not increase at all. This finding of differential gain (not a nonspecific overall change) lends more credence to the reliability of the finding of prevalence increase. The most dramatic changes were for oxygen use and gastrostomy. In 1987, 159 children were documented to be using oxygen. In 1990, this number was 293, an 84 percent increase. Gastrostomy use among children rose from 363 in 1987 to 684 in 1990, an 88 percent increase.

The age distribution of technology dependent children between 1987 and 1990 had one specific difference: In 1987, the largest numbers of technology dependent children per year were found in the second year of life, whereas, in 1990, the largest numbers of children per year were found in the first year of life. When we examined the technologies used to see what technologies were contributing to this shift, we found large numbers of children less than 1 year of age using oxygen (61 children) and dependent on gastrostomies (57 children).

The male/female ratio was remarkably similar from 1987 to 1990: 51.4 percent/48.6 percent and 51.8 percent/48.2 percent, respectively. The racial classifications were also very similar: 83.4 percent white, 7.1 percent black, 8.0 percent Hispanic, and 0.8 percent Asian in 1987, compared to 78.2 percent white, 8.1 percent black, 10.0 percent Hispanic, and 1.2 percent Asian in 1990.

For both years, the number of children without access to some sort of educational placement or input (such as early intervention) was only 9.4 percent. The majority at both time points were living at home (75 percent). In 1987, we had not asked about foster placement; we found that, in 1990, the proportion of children in foster placement was 4.3 percent. In both 1987 and 1990, schools were rarely the residence for these children (1.0 percent and 0.6 percent). Substantial numbers of children (12–13 percent) were reported to spend 7 days per week in a hospital or nursing home.

Recommendations

This study shows the continued reliance of medical care providers on technology interventions for children with chronic illnesses. The study points to a tendency for



88

technologies that augment care, such as oxygen supplementation and gastrostomies, to be applied frequently. A careful assessment of the criteria being used for these technologies is needed. While all uses of these technologies may be perfectly justified, it is also possible that the easy application of these techniques is driving the routinization of these practices without clear thinking about the costs and long-term implications associated with their use.

The availability of technology makes its use increasingly popular. Trends documented in this study are likely to continue for some time. It is essential that these trends be monitored in a systematic fashion.

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Articles and Chapters

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Palfrey JS, Carrillo J. 1990. Pediatrics and community service: Challenges and opportunities for the 1990s. *Current Opinion in Pediatrics* 2:895–904.

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Abstracts

None to date.

Presentations

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Palfrey JS, Porter S. The impact of chronically ill children in school. Presented at the National Association of School Nurses annual meeting, Crystal City, VA, June 1989.

Palfrey JS. Community pediatrics. Address to Communities Can! Conference sponsored by Georgetown University, Stowe, VT, June 1990.

Palfrey JS. Community planning for children with high technology needs. Presented at the National Conference of BMCH, Philadelphia, PA, August 1991.

Palfrey JS. Guidelines for integrating children with severe disabilities into schools. Keynote address before the Rhode Island Department of Education, Providence, RI, October 1991.



Palfrey JS. Management of children with medical technology needs in schools. Presented at the Edlaw sponsored Conference on Medically Fragile and Technology Dependent Children, Fort Lauderdale, FL, October 1989.

Palfrey JS. Programs for children dependent on medical technology. Keynote address to Conference on Children on Ventilators in Schools, Henry Viscardi School, Albertson, NY, March 1992.

Palfrey JS. Project School Care. Presented at the Conference on Special Health Care Needs, Columbis, OH, January 1992.

Palfrey JS. School health challenges for the 1990's. Presented at the American Federation of Teachers Association meeting, Washington, DC. May 1990.

Palfrey JS. School programs for adolescents with disabilities. Presented at the Regional Meeting of the Society for Adolescent Medicine, Providence, RI, October 1991.

Palfrey JS. School readiness issues for children with special health care needs. Presented at School Rediness: Scientific Perspectives, Columbia, MD, January 1992.

Palfrey JS. Technology's children. Plenary session address at the American Academy of Pediatrics. Boston, MA, October 1990.

Palfrey JS. Technology's impact. Presented at the Technology's Futures Panel sponsored by Premier Hospital Alliance, Stuart, FL. March 1991.

Porter S, Bierle T, Dietrich L, Palfrey JS. Children assisted by medical technology in education settings: Resources for training. Project School Care, Children's Hospital, Boston, MA, 1992.

Porter S, Palfrey JS. Project School Care. Presented at the National Association of Children's Hospitals and Related Institutions national meeting. Boston, MA, October 1989.



SIDS Loss: Psychosocial Impact and Predictors of Coping

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PROJECT NUMBER

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REPORT NUMBER

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PROIECT PERIOD

09/01/81-08/31/86

Costs*	Year 1	Year 2	Year 3	Year 4	Year
Awarded	†	†	†	†	†
Requested	†	†	†	†	†

^{*} Indirect included † Not available at the time of publication.

SUMMARY

Statement of the Problem

This study focused on parents' psychological reactions to the loss of an infant to sudden infant death syndrome (SIDS), the largest single cause of postneonatal infant mortality. SIDS is a specific disease entity, defined as "the sudden death of any infant or young child, which is unexpected by history, and in which a thorough postmortem examination fails to demonstrate an adequate cause for death." SIDS accounts for approximately one-third of all infant deaths between the ages of 1 week and 1 year, and it has been estimated that anywhere from 6,000 to 10,000 babies die annually of SIDS in the United States alone.

Until recently, this topic has received limited research attention. Most of the available studies have investigated the epidemiology of the syndrome; systematic studies of the psychological reactions to SIDS are rare. There is, however, a great deal of clinical evidence to suggest that adjustment to the loss of an infant to SIDS poses extremely difficult problems for the parents involved. Moreover, the available literature reports that those who come into contact with SIDS parents (e.g., relatives, neighbors, health officials, or police) often show a profound lack of awareness about SIDS, which can have destructive effects on the psychological sequelae of parents.

This project was undertaken in an attempt to document systematically the common parental reactions to a SIDS loss, and to understand the types of reactions that are associated with successful long-term adjustment. What is a "normal" response to such a loss? Is a period of depression following such a loss necessary for long-term adjustment?



5

To whom do parents attribute responsibility for their infant's death, and how is this related to their adjustment to the loss? How do mothers' reactions to their baby's death, and their ways of coping with it, differ from fathers', and what problems does this pose for couples who lose a baby?

Research Questions or Hypotheses

The major purpose of this project was to assess the psychosocial impact of losing an infant to SIDS (i.e., emotional and psychological responses to the loss, and changes in these responses over time), and to identify the predictors of successful adjustment to the loss of an infant to SIDS.

Study Design and Methods

In this longitudinal study, parents who lost a child to SIDS were interviewed at 1 month, 3 months, and 18 months following the death of their infant. This longitudinal design enabled us to assess changes in parents' emotional reactions and behaviors over time, and made it possible to answer a number of important questions, including whether parents go through stages as they attempt to cope with their loss. This design also enabled us to examine the relationship between parents' initial emotional reactions, attributions of causality, religious beliefs, perceived social support and coping mechanisms, and long-term adjustment to the loss.

In order to determine whether repeated assessments changed the adjustment process of SIDS parents, our design also included a comparison group of SIDS parents who were interviewed at the final time point only (the "measurement control group"). Forty-five mothers and their spouses (where applicable) were randomly selected from the eligible population of SIDS parents and were interviewed only once, at 18 months after the death of their infant.

Each mother who had lost an infant to SIDS between January 1983 and December 1984 was sent a letter 7 days after the infant's death describing the study and inviting her participation. The letter also informed these mothers that a project staff member would contact them shortly to describe the project in more detail, to answer their questions, and, if they agreed to participate, to schedule an interview. If parents had no telephone (approximately 20 percent), a home visit to schedule an interview was attempted. When parents were located, mothers were first invited to participate in the research. If a mother agreed and the baby's biological father was living with the mother, the father was also invited to participate.

At each time point, parents in the longitudinal portion of the study were asked questions concerning their emotional reactions, their attributions of blame, their ability to find meaning in their loss, their perceived social support, and their coping strategies. Parents in the measurement control group were asked these questions at the final time point only. All parents were asked questions designed to assess various indicators of coping and adjustment, including physical, mental, and social health, and general well-being. The interview instrument was constructed after consultation with members of the National SIDS Foundation, and included the Affects Balance Scale and a shortened version of the SCL-90. For the majority of the questions, parents were given a set of



92 SIDS LOSS

responses from which to choose. The interview also included several open-ended questions and a few self-administered scales. A path analytic or causal modeling approach was used to determine how the independent variables were related to one another and to the measures of adjustment, and a multivariate analysis of variance with repeated measures was employed to assess changes in these relationships over time.

Study Sample and/or Population

The sample was composed of parents from Cook County, Illinois, and Wayne County, Michigan, who had lost an infant to SIDS. These metropolitan counties were selected because of their high incidence of SIDS deaths. The medical examiner's office in both counties provided us with the names and addresses of all parents whose infants were suspected of having died of SIDS (i.e., cause unclear) within 48 hours of the death. SIDS was subsequently confirmed by autopsy, which is legally required in all suspected SIDS deaths.

A total of 330 infants in Cook County and Wayne County were suspected of having died of SIDS during our study period. (An additional one-third of the parents whose infants died of SIDS during 1983–84 in the counties under study were assigned to the measurement control group and were interviewed only at 18 months after the death of the infant.) Contact was attempted with the 281 mothers who met our eligibility requirements, namely that (1) the death was classified as SIDS on the basis of an autopsy; (2) the mother was English-speaking and at least 15 years of age; and (3) a visiting public health nurse had informed the mother prior to our contact that the infant had died of SIDS. Sixty-nine mothers (24.16 percent) could not be located by the interviewers or could not be scheduled for the first interview during the eligibility period (15–30 days after the death). Forty mothers (14.2 percent) who were located refused to be interviewed. One hundred seventy-two eligible mothers were interviewed at 1 month after their infant's death (61.2 percent of the total eligible, 81.1 percent of those located). Eighty-five of the biological fathers were currently living with the mothers who agreed to be interviewed; 56 (65.9 percent) agreed to participate at 1 month.

Three months after the death, 163 respondents (71.5 percent of the 1-month sample) were reinterviewed. Nineteen parents (8.3 percent) refused our second interview. Two infant deaths (corresponding to 3 parents) were reclassified as non-SIDS (1.3 percent), and 43 parents (18.8 percent) could not be relocated or scheduled for an interview at 3 months.

Eighteen months after the death of the infant, 124 parents (54.3 percent of the 1-month sample) were interviewed a third time. Nineteen (11.6 percent of the 3-month sample) refused our third interview; an additional 20 parents (12.2 percent of the 3-month sample) could not be located or scheduled for an interview at 18 months. These response rates and attrition rates compare favorably with rates reported in other longitudinal bereavement studies.

Findings

We found no evidence to suggest that questioning parents repeatedly about their loss affected their long-term adjustment. No differences were found on any outcome



measure in analyses that compared parents interviewed at three points in time with those interviewed one time only. Thus, we were able to use the longitudinal data to examine several specific issues. We examined the validity of the following common assumptions about the grieving process: (1) A period of distress is inevitable following such a loss; (2) positive emotions are absent following such a loss; (3) distress is necessary for successful adjustment to such a loss; (4) failure to experience distress will lead to later problems; (5) working through loss is important; and (6) recovery and resolution are to be expected following loss. We also focused systematically on the emotional reactions experienced by parents who lose a child to SIDS, ways in which parents attribute blame for the loss, their ruminations following the loss, dyadic adjustment among couples coping with a SIDS loss, the role of open discussion in mediating parental depression following SIDS loss, and the role of religion in parents' reactions and/or recovery from the loss.

Our analyses revealed a number of intriguing findings about the process of coping with a SIDS loss. We found considerable variability in response to the loss; some parents experienced significant distress, while others showed few signs of depression, both shortly after the baby's death and over time. We found no support in our data for the notion that individuals go through stages of emotional response following loss. In fact, positive and negative emotions were very prevalent among SIDS parents and were often experienced simultaneously, even in the first few weeks after the loss. Moreover, our data suggest that failure to experience significant distress following a SIDS loss is not necessarily indicative of pathology. Those parents who exhibited the most distress at the first assessment (3 weeks after the infant's death) were the ones who continued to show adjustment problems at the 18-month interview.

Recommendations

This study has potential benefits for both health care professionals and the populations of SIDS parents in general. Treatment of parents could be improved through greater awareness of their psychological needs. Specifically, normative information concerning the psychological responses to be expected following a grief experience such as SIDS can help outsiders to develop a more empathic response toward these parents. Data obtained in the longitudinal phase of the project will help in the early identification of those individuals likely to have particular difficulty adjusting to the sudden loss of an infant. Such information may also be useful to investigators interested in designing effective psychological interventions for parents who experience a SIDS loss.

Publications

Articles and Chapters

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CONSEQUENCES FOR CHILDREN OF PATERNAL UNEMPLOYMENT

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SUMMARY

Statement of the Problem

The involuntary or unexpected loss of work is associated with mental and physical health problems in adults. Effects of parental work loss on the health and behavior of children, however, have not been well investigated. The 1980–82 recession sparked extensive media coverage and numerous stories on the plight of families of unemployed workers. Congressional committees held several hearings on issues such as unemployment-related child and spouse abuse, crime, health consequences, and the need for medical insurance. Nevertheless, few systematic and rigorous studies have been conducted on the consequences of parental unemployment for children.

Research Questions or Hypotheses

The North Carolina Work and Family Life Project is a longitudinal cohort investigation designed to explore the health and behavioral consequences for children of paternal job loss. The project began in November 1981 with a major grant from the W.T. Grant Foundation of New York. The grant supported development of instruments, selection of a site, collection of three waves of data on approximately 120 families, and initial exploratory analysis. Support from the Maternal and Child Health Bureau has supported longitudinal analysis of the data.



The major objectives of this project were to:

- 1. Document the incidence of health and behavioral outcomes for children experiencing paternal job loss;
- 2. Document the mental and physical health consequences for the unemployed father and his spouse;
- 3. Examine the modifying effects of social support on the above consequences;
- 4. Examine the influence of job loss on economic circumstances, family roles, and family routines; and
- 5. Examine the effects of changes in economic circumstances and family roles and routines on the health and behavior of family members.

Study Design and Methods

This longitudinal study investigated the consequences for children of paternal job loss in 116 families. Approximately half of the fathers experienced an indefinite layoff or plant closing several weeks prior to their first contact with the project. Each parent was interviewed on three occasions. In addition to demographic information, data were gathered on adult and child life events, child health and behavior, adult physical and mental health, family roles, family routines, and adult social supports and networks. Special attention was paid to adult work histories and economic conditions. Two types of analysis were performed. The first set involved analysis of variance with carefully articulated definitions of paternal job status. The second set used ordinary least squares regression to predict adult and child outcomes.

Study Sample and/or Population

The study population consisted of men whose names appeared on layoff lists or work rosters of approximately 30 companies in a metropolitan area of 375,000 in the northeastern United States. In the design of the sample, we attempted to control for certain major psychosocial influences on children by limiting the sample to children between the ages of 18 months and 13 years, in families headed by fathers with blue collar jobs, and in which there were two parents in the home. The father had either experienced an indefinite layoff or termination or was expecting continuous unemployment. Twenty-six percent of the individuals on the layoff lists and work rosters could not be contacted by telephone. Of those contacted, 42 percent were ineligible because they did not meet the study criteria. Of those who were eligible, 29 percent agreed to participate.

Findings

Fathers who experienced job loss exhibited a decrease in mental health and slightly decreased physical health. Mothers were also affected by the fathers' work loss, but not to the same degree. For the children, the trend suggests that illness rates were higher both for children experiencing paternal joblessness and for children experiencing changing paternal job status (i.e., job loss followed by reemployment). Behavior does not appear to be affected. For both fathers and mothers, length of time unemployed contributed to mental health problems. Unemployment per se was not a significant



predictor of fathers' health, but economic and other life events were associated with decreased physical health. For mothers as well, specific employment variables were not predictive of physical health, but economic events in general were predictive. Multivariate analysis of children's health indicated a negative relationship between fathers' employment status and illness rates. Length of time unemployed, particularly interactive with economic strain, was associated with increased behavioral problems.

Recommendations

Ouestions for further research fall into the following two major categories:

- 1. Defining the problem of unemployment:
 - what is the extent of children's exposure to unemployment? Current labor statistics inadequately reflect the number of dependents who experience parental unemployment specifically, or other economic events in general. The fact that most workers have spouses and/or dependent children suggests that such information should accompany the usual economic statistics.
 - b. How do the economic and job characteristics of all adults in a household influence children? Since most children reside in families with two adults, it is important to delineate the contributions of each adult to the child's environment. Loss of work by one parent may have different effects on children depending on the employment circumstances of the other parent. Further, the economic environment for the child consists of many components in addition to parental employment status. Income, availability of benefits (particularly health insurance), job security, satisfaction with income, and other parameters help to define the economic environment. These same components can be used to characterize the community economic environment as well. As seen in this study, the community, though faced with a very large and rapid increase in unemployment, seemed to cope reasonably well, at least as far as the children were concerned. The issue of job loss in a single-parent family involves different combinations of these components and should be explored separately.
 - c. Do the short-term and long-term consequences of parental unemployment differ? There are two aspects to this question. First, a single, short exposure to unemployment probably has different effects than multiple exposures or long-term joblessness. Second, while the short-term consequences of parental job loss may not be pronounced, this study provides no data to examine the potential long-term consequences.
- 2. Understanding the effects of the economic environment:
 - a. What economically stimulated family processes influence children's health and behavior? Life events were most closely associated with changes in "other" routines. These routines included sharing meals, quiet times, or family activities; visiting friends; or parents' spending time together. These routines were then associated with the mental health of the parents. Family roles, whether family-oriented or child-oriented, were not strongly associated with life events or health and behavioral outcomes.



b. What interventions would ameliorate the effects of unemployment on fathers and mothers? While a body of literature is emerging to describe interventions to assist adults who experience job loss, virtually no studies have addressed the effects of those interventions on children. Difficulties in analyzing the effects of interventions on family members in general (and on children in particular) are analogous to difficulties in analyzing the effects of changing economic circumstances. Interventions such as support groups, job counseling, and retraining may assist workers, but the effects of those interventions on children are probably not straightforward.

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102

GRANDFATHER INFLUENCE ON YOUNG CHILDREN OF TEENAGE MOTHERS

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SUMMARY

Statement of the Problem

The research literature provides strong evidence that children born to adolescent mothers have cognitive and academic deficits; there are indications of nonadaptive social functioning as well. For example, these children tend to perform more poorly on intelligence and achievement tests and tend to be more impulsive and distractible than peers born to older mothers. A 17-year followup study of women who had given birth as adolescents described the condition of their children as one of massive school failure. With approximately half a million babies born to adolescent mothers each year, these findings indicate that there is an enormous waste of human potential. The problem is likely to increase in the coming decade as the birth rate among unmarried adolescents continues to climb.

Fathers cannot be viewed as a resource to these babies since only about 27 percent of adolescent mothers in the United States are living with a spouse 1 year after giving birth, and few of the fathers who do not live in the home have close contact with their children. In fact, the absence of a father figure may contribute to the children's deficits. The literature suggests that fathers exert a positive influence on their young children's socioemotional and cognitive development, particularly when the men are nurturant or take an active role in parenting. In view of these findings, one possible approach to reducing the problems of the adolescent's child is to determine whether her own father



^{*} Indirect included

can fill the role of surrogate father to his grandchild and foster the child's development by virtue of his own nurturant participation in child care. It is also likely that such active parenting by the grandfather will reduce stress on the adolescent through the sharing of child care responsibilities. This form of social support may result in more responsive, sensitive maternal behavior which is predictive of enhanced infant functioning. In addition, the grandmother of the adolescent's baby is likely to feel less burdened when her husband participates in caring for their grandchild, and to become a more nurturing grandmother. The outcomes for the infants are likely to be beneficial under these circumstances.

While it is theoretically possible for positive consequences to accrue for the young children of adolescent mothers when grandfathers take on a surrogate father role, these outcomes have never been demonstrated empirically. The purpose of this project was to determine whether nurturing or significant amounts of grandfather involvement in the rearing of adolescent mothers' young children is associated with enhanced cognitive development and more adaptive social functioning in the children. If the results are positive, and are replicated in other investigations, there are major implications for health delivery service to mothers and children. The number of families potentially involved in such services would not be trivial. Data collected by various investigators suggest that 30–50 percent of all adolescent mothers live with two parents in the first few years after giving birth.

Research Questions or Hypotheses

This study tested the following hypotheses related to grandfather influence on young children of adolescent mothers:

- 1. The greater the quantity of grandfather involvement with the young child of the adolescent mother, the higher the level of cognitive development and the more adaptive the socioemotional functioning of the young child at 12 and 24 months of age.
- 2. The better the quality of grandfather involvement with the young child of the adolescent mother, the higher the level of cognitive development and the more adaptive the socioemotional functioning of the young child at 12 months and 24 months of age.

In addition, the following questions were explored:

- 1. Will the quality of the adolescent's interaction with the child and the quality of the grandmother's interaction with the child mediate the relationships described in questions 1 and 2 above?
- 2. Will the relationships described in questions 1 and 2 above be mediated by the amount of social support the adolescent mother perceives that she is receiving from her father?
- 3. What effect do demographic variables have on the influence of grandfather involvement in child care on child outcomes?
- 4. Is there a difference in terms of child outcomes in having a grandfather present or not present?
- 5. What is the relationship between quantity of grandfather involvement and quantity of caregiving by the child's biological father?



Study Design and Methods

A total of 107 working class families participated in the study. In 66 homes, a grandfather was the sole adult male present; in 41 homes, there was no grandfather or any other adult male. All families contained an adolescent female, her child (age 1 or 2 years at the time of child assessment), and at least one grandparent. Seventy percent of the children were 1 year of age and 30 percent were age 2; 62 percent were white and 38 percent were minority. The grandparents were interviewed individually at home and then each was videotaped in a 10-minute play interaction with the child. The adolescent was interviewed and videotaped in the same type of play interaction at a university laboratory (Merrill-Palmer Institute) where a battery of instruments was also administered to the children. Included in the set of instruments were two cognitive measures (the Bayley Scales of Infant Development—Mental Scale, and Mastery Motivation), and three socioemotional measures (security of attachment to the mother as assessed by the Ainsworth Strange Situation Procedure, compliance with maternal requests, and negative affect). Coding schemes which had been utilized in other investigations were used to derive scores for the above child measures.

Scores for the amount of grandfather involvement, adolescent perceived family support, family conflict, and demographic variables were determined through responses of the adults to a lengthy questionnaire. The quality of the grandfather's, grandmother's, and adolescent mother's interaction with the child was assessed through the use of a validated coding system which called for adding the frequency of occurrence of 17 observed specific behaviors categorized as nurturant for theoretical reasons.

Study Sample and/or Population

The study was restricted to adolescents living with at least one of her parents, or a parent figure, and her baby under 2 years of age. To reduce extraneous variability, the sample was further restricted to families in which (1) the infants did not have low birthweight, (2) the grandfather, if present, was the sole adult male in the family, (3) the adolescent was 18 or younger when the baby was born, (4) the target infant was the adolescent's firstborn child, and (5) the infant would be 1 or 2 years of age at the time of the assessment. The sample was obtained primarily from public schools offering special programs for pregnant and parenting adolescents residing in seven counties in the metropolitan Detroit area.

The final sample consisted of 107 families; of these, 66 (62 percent) had a grandfather present and 105 had a grandmother present. The male figure in the family was the adolescent's father in 61 percent of the sample, the stepfather in 36 percent, and her grandfather in 3 percent. Seventy percent of the babies were 1 year of age, and 30 percent were 2 years, almost equally divided between male and female. The ethnic composition was 62 percent white, 33 percent black, and 5 percent other (e.g., Asian, American Indian). In the total sample, the mean ages of the adolescent, her mother, and her father were 17.5 years, 42.3 years, and 45.2 years, respectively. The average Hollingshead family class index was 32.4, which represents skilled craftsmen and clerical and sales workers. The mean education on the Hollingshead scale for adolescents, grandfathers, and grandmothers were 3.23, 3.82, and 3.92, respectively (3 signifies to 10th



or 11th grade completed and 4 signifies high school graduate). Four grandfathers and 35 grandmothers were not employed (16 in the 66 grandfather-present families and 19 in the 41 grandmother-present families).

The mean occupational ratings on the Hollingshead scale for the employed grandfathers and grandmothers were 3.76 and 4.54, respectively (4 refers to skilled manual workers and craftsmen, and 5 refers to clerical and sales workers). The mean number of hours worked by the grandfathers and grandmothers were 49.2 and 37.1, respectively. Data were also collected about the public assistance received by the families: 29 percent were receiving Aid to Families with Dependent Children, 27 percent were receiving food stamps, 2 percent were receiving general assistance, and 53 percent were receiving Medicaid.

Findings

There was partial support for the two hypotheses. The quality of grandfather involvement was predictive of the amount of child compliance with maternal requests: The more nurturant the grandfather's behavior, the more cooperative the child. The quantity of grandfather involvement was negatively related to negative affect displayed by the child: The more involvement, the less negative affect. For children 1 year of age considered alone the same pattern held, but not for 2-year-olds. In this subgroup, the greater the grandfather's participation in child rearing, the higher the child's Mental Development Index (MDI) score on the Bayley Scales of Infant Development. In all the computations above and those to be discussed below, race and other demographic variables were controlled when these factors were significantly related to any child or adult measure in the analysis.

With respect to the questions posed, it was found that adolescent mother nurturance mediated the relationship between grandfather nurturance and the child's compliance with maternal requests. The greater the grandfather's nurturance, the greater the adolescent mother's nurturance, and the greater the adolescent's nurturance, the more cooperative the child. For 1-year-old children, the same pattern held, and, in addition, greater maternal nurturance was associated with greater security of attachment in the child. Neither the adolescent's perception of grandfather support nor grandmother nurturance functioned as a mediator; neither variable was associated with any child measure.

There were no differences in the child measures when children in families with and without a grandfather present were compared. However, adolescents' scores for maternal nurturance were higher when their fathers were in the home, and the young mothers perceived more conflict in the family. The frequency with which the child and the biological father spent time together was unrelated to the amount of grandfather involvement in child rearing or whether he lived in the home. The only demographic variables to correlate significantly with amount or quality of grandfather participation were his hours of employment and the family's receipt of Aid to Families with



Dependent Children. These factors were negatively associated with the amount of grandfather participation in child care, but even when they were controlled, the quantity of grandfather involvement was predictive of less negative affect in the grandchild. The children's average scores on the Mental Development Index of the Bayley Scales of Infant Development were within the normal range, and the proportion of securely attached babies resembled the proportion found for middle-class infants.

Finally, through the use of exploratory path analyses, the predictors of adolescent mother nurturance were examined, since this variable has been found repeatedly in the literature to be predictive of adaptive child outcomes. Different patterns emerged in families with and without grandfathers. When grandfathers were not in the home, greater grandmother nurturance was predictive of greater adolescent maternal nurturance. However, in homes with grandfathers, only grandfather nurturance functioned as a predictor of adolescent nurturance; grandmother nurturance became irrelevant.

These findings, along with the data indicating that grandmothers' behavior had no direct or indirect effect on the child measures whereas grandfathers behavior did have such an effect, led to the tentative conclusion that grandfathers living in three-generational families as the sole adult male appear to be more salient and influential than grandmothers insofar as the adolescent daughter's maternal behavior and her child are concerned. The differential impact of grandfathers and grandmothers in these homes may be at least partially attributable to the unique role played by the grandfather in the family. The grandmother's child rearing functions appeared to be redundant to those performed by her daughter, who was the baby's primary caregiver in this study more than 50 percent of the time the child was awake. If the baby's father had resided in the home, perhaps the grandfather's impact on the child might have been as minimal as his wife's influence appeared to be.

Recommendations

There is clearly a need for replication of this study and for longitudinal investigations. However, in view of the positive short-term effects that the grandfather's behavior appears to have on both his grandchildren and his adolescent daughter, it is suggested that efforts be made to develop a small-scale demonstration program for three-generational families incorporating a grandfather as the only adult male, an adolescent mother attending school, and her baby under 2 years of age. The goal would be to foster the grandfather's nurturant behavior with the child and promote his participation in child rearing. The most effective strategy is likely to be a male-to-male approach in which grandfathers who are warm, involved in child rearing, and similar to the target population in age and social class, serve as role models and facilitators.

It is recommended that these model grandfathers reach out to the grandfathers in their neighborhoods and meet with them on a one-to-one basis in their homes using a variety of means to engage them in activities with their adolescent daughter's baby. Small groups of such men can gradually begin meeting with their grandchildren and participate



in some joint activities, perhaps taking the children to a park or playground. Agencies that have considerable contact with adolescent mothers, such as public health departments and schools, could best serve as the central organizer of such programs.

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Abstracts

None to date.

Presentations

McNair S. Radin N. Gender differences in nurturance in grandparents of young children of teen mothers. Presented at the biennial meeting of the Society for Research in Child Development, Seattle, WA, April 1991.

Oyserman D. Radin N, Saltz E. Determinants of nurturant parenting in teen mothers living at home. Presented at the biennial meeting of the Society for Research in Child Development, Seattle, WA, April 1991.

Radin N, Benn P, Oyserman D. Dynamics in a three-generational family: A teen, her father, and her baby. Presented at the National Conference on Family Relations, Seattle, WA, November 1990.

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IMPROVING MEMORY OF EMR CHILDREN

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PROJECT NUMBER MCJ-260554

REPORT NUMBER MCH/CCS-91/04

NTIS NUMBER PB92-135573

PROJECT PERIOD 07/01/87-12/31/90

Year 4 Year 5 Costs* Year 1 Year 2 Year 3 34,090 n/a n/a 85.095 89,429 Awarded n/a 127,957 134,646 33,689 n/a Requested

SUMMARY

Statement of the Problem

This study assessed the effectiveness of a variety of instructional techniques designed to facilitate the performance memory of inner-city preschoolers and school-age retarded children across time and situation. Once identified, successful techniques will have wide applicability as teaching tools in the classroom, in intervention programs or demonstrations provided by early childhood specialists and educators, and in improved parent-child interactions. Although the primary purpose of the study did not address issues related to gender or race, the relevance of these factors for memory intervention might possibly be explored through some secondary analyses of the data.

Evidence suggests that facilitation of cognitive functioning may permit more normal levels of functioning in society for those who already suffer cognitive deficits or delays and for those who are at risk for developing learning problems. For instance, educable mentally retarded children are at high risk for failing to achieve independent levels of maintenance in the culture. Improving cognitive functioning in areas such as memory may be one of the crucial factors in assisting an educable mentally retarded child to achieve a more normal and independent level of functioning as an adult. In addition, determining whether these techniques are effective for urban preschoolers who are at greater risk for cognitive delays, and assigning these children to special education classes may reduce the need to intervene later.

Research Questions or Hypotheses

This project studied the applicability of new models of cognitive development to memory instruction for inner-city preschoolers and older school-aged mentally retarded



^{*} Indirect included

children. This study was carried out both to advance instructional techniques devoted to memory enhancement and to further theoretical specification of the processes involved in learning and memory.

Study Design and Methods

To identify and develop effective memory-enhancing techniques, 106 preschoolers of average ability and 99 educable mentally retarded children ages 7–10 years participated in this study in one of six training conditions with an experimenter approximately twice a week for 2–3 months. In all conditions, children participated in playful activities (e.g., coloring pictures, playing with blocks). In four of the conditions, children were then asked to recall certain aspects of the activities. The extent to which the experimenter provided explicit strategy instruction and scaffolding (i.e., assistance in helping children recall) was varied across these four conditions. In two of the conditions, children received explicit instructions concerning the best way to recall (strategy instructions) and in the other two, no strategy information was given (no strategy instructions). Within each of the strategy conditions, the amount of scaffolding was varied: Children either received prompts to aid recall or no prompts were given. Before and after training, a wide variety of children's memory skills were assessed to determine how much improvement occurred across conditions.

The training conditions tested in this study were generated from correlational findings obtained previously by the principal investigator. These findings showed that certain patterns of maternal stimulation were significantly related to superior memory performance in young children. These patterns of stimulation involved placing memory demands on the children, such as asking questions requiring recall (e.g., Where are your shoes? Where did you go with Grandma? What is the animal called?), in the course of conversation and play involving mother and child. These questions elicited scaffolded recall and may have encouraged development of appropriate strategies for remembering. The question of whether demands contributed to memory development was tested experimentally in the current study.

Children asked to recall information were expected to perform better than those who received no memory demands, and those who received more scaffolding during recall (i.e., prompts) were expected to improve most. These children were expected to learn the routines used by experimenters to aid in recall (i.e., prompting) when remembering independently on their own during the posttest. Prompting, however, may not be necessary to produce memory improvement; merely requiring children to recall frequently—providing practice—may be sufficient to boost memory skills. By comparing posttest performance across conditions, the relative contribution of instruction components was assessed.

Evaluating the effects of strategy instruction on memory improvement provided an opportunity to compare the contributions of newer Soviet theories to more traditional American perspectives, in which strategy instruction is emphasized. Soviet psychologists have suggested that children first develop intentional memory skills in familiar and meaningful tasks such as games in which memory is not a goal in itself. They hypothesize that young children do not conceive of remembering as an activity in its



own right—remembering just for the sake of remembering—as is often the case in school or laboratory tasks. Instead, young children are thought to remember in order to accomplish some other goal (e.g., finding a lost toy, locating the cookie jar, talking with friends) and only gradually come to develop the intention to remember, transferring their skills from one type of situation to the other. If this is true, younger children should not benefit from memory instruction, because remembering would be separated as an activity from the larger context, such as the games children played in the present study. Instead, children should benefit most from the memory games in which no memory instruction was provided.

Study Sample and/or Population

Study subjects were average-ability preschool children ages 4–5 years and retarded elementary school-age children in an urban setting. These two groups were selected because their intentional memory skills are poorly developed; they are at risk for developing, or have already developed, learning problems; and they need assistance in making the transition between use of involuntary and voluntary (intentional) memory skills. Because these children's skills are in the process of changing, they are perhaps more susceptible to the effects of instruction (particularly when embedded within less-structured play settings) than older or less delayed children. This permits a better test of theoretical models of memory processing, the effectiveness of intervention, and specification of those instructional components most successful in promoting development.

The average age of the preschool children was 4 years 5 months, with a mean mental age of 4.0 years. The average age of the retarded children was 8 years 5 months, with a mean mental age of 4.5 years. An approximately equal number of girls and boys participated in each group. Among the preschoolers, there were 54 girls and 52 boys; among the educable mentally retarded children, there were 44 girls and 55 boys. Of the preschoolers, 78 were black, 26 were white, and 2 were Asian; of the educable mentally retarded children, 91 were black and 8 were white.

An additional 26 preschoolers and 13 educable mentally retarded children initially participated, but were eliminated from the study because they moved, their attendance was erratic, they were removed from school by their parents, their parents no longer wished them to participate, they refused to cooperate, or because of experimenter error (incorrect training or pretest procedures). Finally, 29 preschoolers and 14 educable mentally retarded children were not selected for the study due to high scores on the pretest.

The educable mentally retarded children were recruited from 18 schools located throughout the Detroit Public School system. Children in this group met three criteria: (1) Identification by the local school district as educable mentally retarded and in need of special education services within that category; (2) chronological age between 7 and 11 years; and (3) approval from parents and classroom teachers to participate in the study. Children with autism, Down syndrome, speech impediments, or under medication (N=5) were excluded from the study.

Preschool children were recruited from 13 child care centers (12 located within the city and 1 in a suburban area). Children in this group were (1) Ineligible for any special



education services as determined by the local school district, (2) between 4 and 6 years of age, and (3) approved by their parents and classroom teachers to participate in the study.

Findings

Children's memory performance was found to be sensitive to variations in play and conversation. However, predictions derived from Soviet models of cognitive functioning received mixed support. Techniques leading to greatest improvement seemed to be those representing a combination of different approaches.

First, memory demands were not typically necessary to improve recall and strategy use. Only educable mentally retarded boys given memory demands and prompts seemed to recall more in comparison to baseline play interactions. Furthermore, other skills were influenced by memory practice only when no strategy information was available: Certain types of errors in recall were reduced by memory demands, and organization of information during recall was greater when memory demands were given, at least for the retarded children. Thus, more structured activities may be helpful for some children, but most will learn to recall more effectively in the absence of specific recall demands. Still, these results indicate that memory processes can develop in the context of playful activities and suggest that social interactions between adults and children contribute to children's memory skills.

More critical to enhancement was strategy instruction, especially for recall of object names. Children who received strategy information organized their recall more, searched their memories more, and were less likely to make recall errors. Furthermore, these effects were similar for preschool and educable mentally retarded children. These findings indicate that strategy information can be introduced into play contexts to improve memory skills, even for young and delayed children, and that children, at least by age 4, can conceive of remembering as an activity separate from other goals. Currently, explicit memory instruction is not incorporated into preschool programs and parents do not typically provide much direct memory strategy information. These results indicate that this type of instruction needs to be incorporated into a variety of teaching interactions. Interestingly, memory facilitation can occur in the absence of recalling information; children who were told how to remember, but were never asked to recall, improved as much as children given memory practice. This finding has important implications for classroom activities: Information about how to remember can be effective even when introduced into group exercises. If recall practice is not necessary for improvement, monitoring of individual performance is not required.

One of the most significant findings was that children, especially preschoolers, who were able to reenact more of the experimenter's routine (in many cases independent of training condition) improved more. When children were given a chance at the end of training to "be the teacher," children who demonstrated they had learned more of the experimenter's role recalled more during the posttest. Thus, children who had more successfully internalized the interaction between themselves and the experimenter improved more, even on new tasks they had never encountered during training. These results indicate that even young children can improve their recall if learning of the



instructor's role or perspective occurs, and suggest that barriers to learning which young or delayed children encounter may involve perspective-taking skills. Thus, memory-enhancing activities should be structured so that children can exchange roles with the instructor, further encouraging them to take on the perspective of the more knowledgeable expert. In future research, effective techniques for encouraging role-taking need to be identified.

Recommendations

The effectiveness of these instructional techniques for inner-city preschoolers and young school-age educable retarded children indicates that parents, teachers, learning specialists, and early child care providers should be trained to provide certain kinds of interactions and activities that promote memory skills. In so doing, lags in cognitive development typically experienced by these children would be reduced.

These findings perhaps have greatest implications for mental health care providers who deliver services to families within the home. Recently a report prepared by the General Accounting Office for the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Senate Committee on Appropriations indicated that home visiting, in comparison to other approaches, was a more promising early intervention strategy for at-risk families. Because the memory techniques developed here can easily be integrated into parent-child interactions, because parents influence their children's development much earlier than teachers or child care providers, and because home health workers, such as infant mental health specialists, interact earlier with parents than other providers, training in memory stimulation techniques should especially target this group of care providers.

Memory-enhancing techniques can be incorporated into playful or more organized activities and should include the following:

- 1. Step-by-step instructions should be given, describing how information should be retrieved using category membership, temporal ordering, or imagery as cues depending on the nature of the target information to be recalled. Explanation of the strategy's function (i.e., it works to increase recall) should be incorporated.
- Questions requiring recall should be added, although overemphasis on questioning as a technique should be avoided. In other words, the instructor should use questioning when useful, but should not engage in questioning just for its own sake when the child appears uninterested or frustrated by the questioning routine.
- 3. Independent of questioning, activities that are supportive of memory activity, such as categorization, should be practiced.
- 4. Delivery of all techniques should involve turn-taking between the adult and child so that the child has the opportunity to practice the adult's expert role. Individual and classroom activities should be constructed around role-taking.

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Presentations

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ANTHROPOMORPHIC STANDARDS FOR THE EVALUATION OF GROWTH AND NUTRITIONAL STATUS

GRANTEE

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PROIECT NUMBER

MCJ-260560

REPORT NUMBER

MCH/CCS-91/02

NTIS NUMBER

PB92-135532

PROIECT PERIOD

10/1/87-09/30/89

Costs*

Year 1

Year 2 Year 3 Year 4

Year 5

90,144

no cost

Awarded

n/a

n/a

n/a

Requested

91,561

no cost n/a

n/a

n/a

extension

extension

SUMMARY

Statement of the Problem

Current anthropometric standards used in evaluating nutritional status of children and adults do not provide information on body composition, and, thus, are not effective for distinguishing the truly malnourished from the simply underweight, and the obese from the normally heavy. There is a critical need for a more timely anthropometric standard that is not population-specific but that can permit the evaluation of growth and the components of excessive weight and underweight, and can therefore determine the nutritional status of children and adults.

Research Questions or Hypotheses

The purpose of this study was to present descriptive information (means, standard deviations, and percentiles) by age, gender, and frame size, of anthropometric dimensions of body size and body composition used in evaluating growth and nutritional status of children and adults.

Study Design and Methods

This study is based on a cross-sectional sample of 43,774 subjects ages 1–74 years, derived from the first (1971–74) and second (1976–80) National Health and Nutrition



^{*} Indirect included

Examination Surveys (NHANES I and NHANES II) conducted by the National Center for Health Statistics. The study includes measurements of weight; height; sitting height; elbow breadth; mid-upper arm circumference; triceps skinfold thickness; subscapular skinfold thickness; computation of mid-upper arm muscle and fat area and arm fat index; and calculation of sitting height index, body mass index, and frame size.

Study Sample and/or Population

The NHANES I was conducted according to a multistage, stratified sampling approach that included the selection of 28,043 persons ages 1–74 years, representing the 194 million noninstitutionalized civilians in the United States. Of the 28,043 individuals who comprised the sampling universe of NHANES I, 23,808 (84.9 percent) were included in the present study.

The NHANES II was conducted following the same sampling and data collection methods as NHANES I. The stratified probability sample included the selection of 27,801 persons ages 6 months to 74 years who represented the population of 196 million noninstitutionalized civilians in the United States. Of the 27,801 individuals who comprised the sampling universe of NHANES II, 20,322 (73.1 percent) were interviewed and examined. Hence, the present study includes a total sample of 44,130 (23,616 from NHANES I and 20,158 from NHANES II).

The distribution of the height and weight of the NHANES I subsample, when appropriately weighted for sampling variability, was indistinguishable from that of the NHANES II subsample. For this reason, and in view of the critical need for a large sample size, we decided to merge the data of NHANES I with NHANES II, treating them as a single sample. To do so, we calculated a new sampling weight by dividing each subject's sampling weight by two, as recommended by the National Center for Health Statistics.

The total combined sample of NHANES I and II surveys consisted of a sample population of 7,125 blacks; 35,931 whites; and 718 persons of other ethnic groups. They ranged in age from 1 to 74 years. However, as shown below, the number of cases was not the same for all the anthropometric dimensions.

Table 1. Sample size distribution by ethnic group in the combined samples derived from NHANES I & II surveys

Variables	Blacks	Whites	Other	Total
Age	7,125	35,931	718	43,774
Weight	7,122	35,904	718	43,744
Height	6,954	35,436	708	43,098
Sitting Height	6,736	34,637	681	42,054
Elbow Breadth	7,119	35,881	718	43,714
Arm Circumference	7,116	35,864	718	43,698
Triceps Skinfold	7,080	35,801	716	43,597
Subscapular Skinfold	7,052	35,694	714	43,460



Findings

The statistical analysis yielded the following:

- 1. A general protocol for obtaining anthropometric measurements compatible with the present standards;
- 2. Descriptive information (means, standard deviations, and percentiles) by age, gender, and frame size, of anthropometric dimensions of body size and body composition used in evaluating growth and nutritional status of children and adults;
- 3. Illustrations of the use of statistical criteria for classifying the anthropometric dimensions of children and adults into five categories of growth and nutritional status; and
- 4. Illustrations and practical examples of the use of anthropometric dimensions in diagnosing the nutritional status of clinical and nonclinical populations.

Recommendations

All evaluations of growth and nutritional status should be conducted with reference not only to height and weight but also to measures of skinfold thickness and muscle mass. Assessment of undernutrition should be conducted when the values for muscle mass and height are below the 5th percentile. Assessment of overnutrition, or obesity, should be performed when the values for skinfold thickness exceed the 85th percentile.

PUBLICATIONS

Articles and Chapters

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Abstracts

None to date.

Presentations

None to date.



COST OF FOLLOWUP CARE FOR PREMATURES

GRANTEE

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PROJECT NUMBER

MCJ-360511

REPORT NUMBER

MCH/CCS-89/08

NTIS NUMBER

PB90-147984

PROJECT PERIOD

Awarded Requested 10/01/84-09/30/88

Costs*

Year 1	Year 2	Year 3	Year 4	Year 5
84,688	102,626	91,138		n/a
96,604	101.959	93.010		n/a

^{*} Indirect included

SUMMARY

Statement of the Problem

Intensive care was introduced to the newborn nursery nearly two decades ago. Since then, neonatology has become the largest pediatric subspecialty at most medical centers, and regionalization of high-risk newborn care was widely introduced. Advances in parenteral alimentation, surfactant therapies, and other treatments have been made. The effect of these and other changes on child health as measured by infant mortality, and particularly perinatal mortality, was dramatic. Infant mortality fell from 26.0 deaths per 1,000 live births in the 1960s to 9.9 per 1,000 in 1987.

While these figures are encouraging, some concerns about infant mortality rates persist. Black infant mortality was twice the rate for white infants in 1960, and it was still double the white rate in 1985. The proportion of late neonatal deaths (7–27 days) increased at the expense of early neonatal deaths (less than 7 days). Furthermore, the proportion of postneonatal deaths (28 days to 11 months) increased while neonatal deaths fell. The postponement of deaths and the increased morbidity among survivors required careful attention. Long-term followup became a necessary adjunct service of neonatal intensive care units. As long as the costs and benefits of the new services contained some degree of uncertainty, a responsibility for followup of survivors remained.



Research Questions or Hypotheses

The research objective of this study was to evaluate a regionalized perinatal program's impact on the population served in terms of additional care needed to compensate for prematurity and its sequelae. This research complemented ongoing followup efforts which are currently components of the service program. The main focus was on utilization of inpatient and outpatient services by graduates of the neonatal intensive care unit, up until school entry. With permission, school records will be accessible for neonatal intensive care unit graduates who have entered school.

Population-based epidemiologic studies are not easily adaptable to specific hypothesis testing, since they are observational rather than experimental. However, the following general expectations guided the research:

- 1. Rehospitalizations of premature infants are much more frequent than those of term babies, but not all of these readmissions are due to perinatal morbidity. Many readmissions are due to the fact that premature infants come from a population that is generally at higher risk for morbidity.
- 2. Minor morbidity cared for in ambulatory settings is higher for neonatal intensive care unit graduates than for those of the regular newborn nursery. Only part of the excess morbidity is due to perinatal morbidity; the remainder is due to the high-risk nature of the population from which neonatal intensive care unit graduates come.
- 3. Morbidity differentials between neonatal intensive care unit graduates, matched controls, and the remaining children decline rapidly with increasing age.
- 4. The few newborns requiring intensive care (approximately 4 percent) account for most of the nursing costs (about 90 percent) and for the majority of all care up to age 1 (about 70 percent); however, these infants account for only a small portion (less than 10 percent) of all care after age 1. Only a minor portion of costs are covered by out-of-pocket payments.

Study Design and Methods

This research project focused on the long-term outcome of neonatal intensive care in the context of the total child population. Need for additional medical services, and the concomitant increased costs, represented one aspect to quantify. The study design was based on social epidemiology (i.e., following total cohorts of children in one community over all preschool years). Community-wide data bases on all children (the register of birth certificates), all inpatient utilization by children (register of all child admissions in the community), and all ambulatory utilization of a sample of children who graduated from the neonatal intensive care unit were compared to matched controls. A computerized neonatal tracking program and the Perinatal Data Register at the nine-county regional tertiary center in upstate New York were the entry points for the study.

Study Sample and/or Population

The study consisted of Phase I (1980–83) and Phase II (1984–86) components, with most of the work focusing on Phase I. During Phase I, a total of 2,664 infants were discharged from the neonatal intensive care unit, and about 75 percent could be



followed at least partially by the neonatal tracking program. Ambulatory care was monitored for 1,039 children seen in 4 large group practices or health centers. Inpatient care was monitored for 2,486 neonatal intensive care unit graduates and 4,452 controls, for a total of 27,038 patient-years.

Findings

The study findings appear encouraging despite major methodological difficulties. First, the followup rate through mailings to patients and pediatricians for a 5-year period was not as high as we had hoped. The returns are strongly biased toward those of higher socioeconomic standing. In the low-income population, geographic mobility poses a major problem for followup and casts doubt on the possibility of tracking former patients through mailings to parents and providers alone. A formal linkage with schools or other nonmedical institutions may be necessary. Second, data systems are rarely maintained with sufficient precision to allow followup over time and across providers. Ideally, a sequence of events such as birth, transport to tertiary neonatal intensive care unit, back transport to hospital of delivery, discharge, and readmission would leave a systematic trail of data in the various service files from which utilization histories could be constructed for cases and controls. The difficulties encountered in tracing patients through the system were larger than anticipated.

Nevertheless, when compared to the control group, excess ambulatory utilization by cases was minor and of short duration. In fact, only 20 percent excess utilization for 2–3 years was observed in settings with easy access to care. After that period, there appeared to be a hardiness/selection effect rather than an increased morbidity effect, and, in some instances, cases may need less care than controls. No excess utilization was observed in low-income populations. Such crossover may also be present for long-term inpatient followup. A small number of cases required repeated admissions over a longer period of time than previously reported. We observed excess utilization for 5 years but none after 6–7 years.

Recommendations

Despite the successful introduction of neonatal intensive care, the U.S. infant mortality rate remained at an unacceptably high level among all the industrialized countries during the study period. While there is a tendency to take pride in having the lowest weight-specific perinatal mortality rates, this only shifts the focus to the high rates of prematurity and low birthweight babies in the United States compared to other industrialized countries. It also should direct our attention to other negative indicators like the high rate of adolescent childbearing in the United States compared to other industrialized countries. The reason for these problems, as shown in cross-national and cross-cultural studies, is inherent in our society. Social and genetic factors appear to outweigh the impact of health service delivery. In the field of pediatrics, the limits of health care have become especially evident.

No conclusion can yet be drawn about the long-term functioning of neonatal intensive care unit graduates in school. Their occupational careers have not yet been examined. Case control studies rather than prospective cohort studies will be needed to



assess such lifelong effects, and such data will only become available in the 1990s. Although not all of the data have been (or ever will be) compiled, a consensus has emerged about the success of neonatal intensive care unit graduates. Studies are already declining on the efficacy or effectiveness of neonatal intensive care units. The positive effects of our better understanding and management of perinatal morbidity so clearly outweigh any negative effects for some survivors that they are increasingly seen as within the normal range of events. Aggressive neonatal care is no longer controversial.

PUBLICATIONS

Articles and Chapters

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Roghmann KJ, Szilapyi PG. 1993. The new health care market: Health services for children; The utilization of health services: Ambulatory care. In Haggerty RJ, Roghmann, KJ, Pless IB, eds. *Child Health and the Community* (2nd edition) (pp. 408–418). New Brunswick, NJ: Transaction Publishers.

Abstracts

None to date.

Presentations

None to date.



NEONATAL OUTCOME AND WEIGHT GAIN OF BLACK ADOLESCENTS

GRANTEE

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PROJECT NUMBER

MCJ-360534

REPORT NUMBER

MCH/CCS-89/07

NTIS NUMBER

PB90-147992

PROJECT PERIOD

Awarded

Requested

01/01/86-12/31/88

Costs*

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 168,627
 187,184
 103,371
 n/a
 n/a

 168,627
 183,585
 98,849
 n/a
 n/a

SUMMARY

Statement of the Problem

The risk of death within the first 28 days of life is approximately twice as high for the infants of black women as for infants of white women. The infants of young black adolescents are at especially high risk. The excessive mortality of these neonates is almost entirely attributable to low birthweight, the causes of which are unclear. It is not yet known to what extent low birthweight is due to preterm birth and/or to intrauterine growth retardation. Enhancement of fetal growth is a major way to reduce the chances of having a low birthweight infant.

Maternal weight gains of approximately 20–28 pounds during pregnancy are currently recommended by most clinicians. While a weight gain of this magnitude may minimize the morbidity of infants born to adult women of average weight, it may be insufficient to minimize morbidity in the infants of young black adolescents. Greater weight gain during pregnancy for these young mothers may counterbalance the adverse effects on infant birthweight of certain adolescent maternal characteristics, including small maternal size, marginal nutrition, and lifestyle.

Since there are potential problems associated with excess maternal weight gain, it is imperative that any recommendations on change in weight gain for young pregnant black adolescents be scientifically based. This study provides data to determine whether there is reasonable evidence to recommend further study of weight gain for very young pregnant black adolescents.

138



^{*} Indirect included

Research Questions or Hypotheses

This study investigated the relationship of maternal weight gain and neonatal outcome (primarily birthweight and gestational age) of black adolescent and adult women of lower socioeconomic status. Total weight gain and patterns of weight gain were determined by comparing young adolescents (less than 17 years of age), older adolescents (ages 17–19 years), and adults (ages 19–30 years) and by controlling for neonatal outcome.

Study Design and Methods

Mothers were weighed and measured throughout pregnancy, using a standard protocol. Personal interviews were conducted to obtain social and medical histories. Nutritional evaluations (including diet history, diet intake, skinfold measurements, and body composition) and laboratory assessments were performed at least twice during pregnancy. The neonates were weighed and measured within 24 hours of birth, using a standard protocol, and Dubowitz evaluations were performed. The primary emphasis in the study was the precise measurement of maternal and neonatal size.

Study Sample and/or Population

Study subjects were 195 low-income pregnant black women who enrolled for prenatal care between February 1, 1986, and May 1, 1988, and who delivered live-born singleton infants at the Strong Memorial Hospital in Rochester, New York. All reported being less than 22 weeks' gestation, and none had medical conditions known to be associated with low birthweight.

Findings

Young adolescents began and ended their pregnancies with lower weights than did older adolescents and adults, although the differences were not significant. Young adolescents, older adolescents, and adults who had appropriate-for-gestational-age term infants gained a similar amount of weight during pregnancy. Young adolescents gained significantly more weight during the third trimester of pregnancy than did older adolescents and adults. The neonates of adults were more likely to be of low birthweight than were the neonates of young and older adolescents, although the differences were not significant.

Recommendations

We believe there is evidence to recommend further study of weight gain for very young pregnant black adolescents, because they start and end their pregnancies smaller in size than do older mothers. What remains to be determined is whether somewhat higher weight gain than currently recommended for young adolescents (resulting in final pregnancy weights similar to those of older adolescents and adults) would benefit these adolescent mothers and their infants. For example, are young women who are small capable of carrying and delivering larger infants? Do larger infants benefit from being larger or are they more likely to have complications resulting from their deliveries?

There are many possible applications of the findings of this study to the delivery of health care:



- 1. Young adolescents had more social and behavioral problems than did older adolescents and adults. Psychosocial intervention, particularly with a focus on the family and on family and patient education, should be a central part of prenatal services rendered to all adolescents, but particularly to young adolescents.
- 2. Young adolescents and older adolescents had high rates of sexually transmitted diseases. Early detection of the pathogens and early treatment of these young people and their partners are imperative in order to protect the fetuses and the mothers from the potentially adverse effects of these diseases. *Trichomonas vaginalis* was a particularly frequent pathogen among our study adolescents.
- 3. On the basis of 3-day diet records, young adolescents were especially at risk for deficiencies of calcium and vitamin D. Both they and their fetuses need calcium for adequate growth. The role of lactose intolerance in the inadequate intake of these nutrients in this population is unclear.
- 4. The infants of adults (low-income primiparous black women) were at high risk for low birthweight and prematurity. The exact reasons are unclear, but a special effort should be made to identify these women early and to enter them into prenatal care.

Older adolescents were also at risk, particularly for high-risk problems of substance use and sexually transmitted diseases. Their infants, however, had the best outcome of all the infants of the three maternal age groups.

The primary policy implication is to reinforce the critical need for prenatal care for disadvantaged pregnant women. Despite their great social risk, the infants of adolescents did relatively well. Their mothers complied with prenatal care, improved their nutrition, decreased substance use, and had their sexually transmitted diseases treated during pregnancy—a reflection of their ability to modify their behaviors. Their infants did relatively well, with a low birthweight rate of 11.2 percent for young adolescents and 10.0 percent for older adolescents, compared with national data for this group of 14.0 percent and 13.2 percent. It is our belief from having worked with pregnant adolescents for nearly 20 years that improvements can still occur in the delivery of health services for groups such as our study population enrolled in prenatal care. For example, we would recommend outreach strategies to identify pregnant adolescents and to urge them to enter prenatal care as early as possible in their pregnancies.

Major improvements in neonatal outcome will occur only as a result of major social improvements in the quality of life for the poor in this country. We must continue to work toward improving the strength and financial capability of families, the quality of the education of our children, and access to excellent prenatal and general health services for children and their families. For adolescents and other high-risk women, we must also work to prevent high-risk pregnancies through adequate contraception and preventive techniques.

Further research suggested from this study consists of both new projects and continued analysis of the data from this study. New projects include those related to adolescent maternal weight gain and neonatal outcome and those related to understanding the high risk of primiparous black adult women having small infants.



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Abstracts

None to date.

Presentations

None to date.



PILOT SCREENING FOR BIOTINIDASE DEFICIENCY IN NEWBORNS

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REPORT NUMBER

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PB89-230817

PROIECT PERIOD

Awarded

Requested

10/01/86-10/31/88

Costs*

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 61,768
 65,110
 n/a
 n/a
 n/a

 61,768
 65,110
 n/a
 n/a
 n/a

SUMMARY

Statement of the Problem

Biotinidase deficiency is an autosomal recessive inherited disease. The enzyme biotinidase is responsible for recycling biotin in the degradation of carboxylases and in the liberation of protein bound biotin in digestion. The symptoms of the disorder result from a deficiency of biotin and the biotin-dependent carboxylases. These include cutaneous symptoms such as skin rash, alopecia, conjunctivitis, and fungal infections; neurological involvement such as seizures, ataxia, hypotonia, hearing loss, visual impairment, and delayed development; and biochemical abnormalities presenting as metabolic acidosis and organic aciduria. Untreated, the condition may be fatal. Physiologic doses of biotin administered orally are effective in the alleviation of biochemical and cutaneous symptoms and can prevent but not reverse neurological dysfunction.

Through early identification of children at risk and prompt intervention, including medical evaluation, diagnostic testing, and parental education, treatment may be initiated before clinical signs develop, permitting normal growth and development. Consequently, affected individuals and their families can be spared the burdens of lower quality of life and higher lifetime costs for health care.



^{*} Indirect included

Research Questions or Hypotheses

The goal of this study was to evaluate screening for biotinidase deficiency for incorporation into the panel of newborn screening tests in New York State.

Study Design and Methods

The method of Heard has been used in screening, with the modification of a 40 percent increase in substrate concentration. This intensifies color development of the reaction and allows for a permanent rather than transient color change. Additionally, the procedure has been adapted to microtiter plates with the results read on a microtiter colorimetric plate reader. The use of transfer plates allows the blood spots to be separated from the microtiter reaction prior to color development. Negative controls are made by combining washed packed blood cells with a plasma substituted albumingamma-G globin in phosphate buffered saline.

Study Sample and/or Population

The population studied consisted of all infants born in New York State from January 1, 1987, to September 30, 1988. All specimens received for routine newborn screening during the period were also tested for biotinidase deficiency.

Findings

The New York State Newborn Screening Program tested 506,794 specimens for biotinidase deficiency from January 1987 through September 1988. Presumptive positive results were identified in 67 cases and second specimen collections were requested. Specimens were received from 63 of these infants (94 percent); 3 infants (5 percent) were lost to followup and there was 1 death due to unrelated causes. Of the second specimens, 59 tested normal and 4 tested abnormal. The infants with abnormal second tests were referred to metabolic disease treatment centers for clinical evaluation and quantitative serum testing. Of these, one was determined to be normal and three were identified as true cases of biotinidase deficiency.

Of the three infants with biotinidase deficiency, one was white, one was black, and one was Hispanic. The distribution of the State population is 60 percent white, 20 percent black, 15 percent Hispanic, and 5 percent other and unassigned. The frequencies among the various populations, therefore, range from 1:67,500 for Hispanics to 1:270,000 for whites. The average age at diagnosis for the cases detected was 48 days. One case had some evidence of mild neurological dysfunction at time of diagnosis, and the other two were asymptomatic.

Analysis of the 59 false positives showed that 61 percent of the cases had one or more complicating factors. These included prematurity (38 percent), transfusion (10 percent), and biohazardous condition, such as a contagious virus (31 percent). The low birthweight rate in New York State is 7.3 percent, yet low birthweight infants accounted for 49 percent of the false positives.

Notices regarding biotinidase deficiency were sent to neurologists, dermatologists, and immunologists throughout New York State offering testing for symptomatic children. Specimens were received from 22 children. One case was identified in a 3-year-old black



girl who presented with skin rash, alopecia, seizures, deafness, severe retardation, and blindness. She had a history of hospitalizations to evaluate her condition and stabilize severe acidotic attacks, but was not diagnosed and treated with biotin until this test became available.

Recommendations

Biotinidase deficiency demonstrates many of the requisites for inclusion in a newborn screening program:

- 1. The assay is suitable for high-volume screening. It is technically simple, inexpensive, and can be done in microtiter plates, a future direction for automating screening programs. Reagents and supplies cost about 2 cents per newborn tested.
- 2. The rate of false positives is low. Many of the false positives were from low birthweight babies who needed retesting for other screened disorders.
- 3. No false negatives were identified. Sulfa drugs which may cause false negative reactions in the assay are not administered in the newborn period.
- 4. The frequency of biotinidase deficiency is within the frequency range of disorders in current screening programs.
- 5. Cases of biotinidase deficiency have been identified in the three largest ethnic categories of the State population.
- 6. Treatment and followup are simple, inexpensive, and effective.
- 7. Early intervention can prevent irreversible clinical sequelae which would otherwise lead to lifetime disability and higher medical costs or early death.

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Abstracts

None to date.

Presentations

None to date.



STRESS, SOCIAL SUPPORT, AND ABUSE AND NEGLECT IN HIGH-RISK INFANTS

GRANTEE

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Costs*

Year 1 Year 2 Year 3 Year 4 Year 5 208,288 210,586 108,750 134,531 n/a 240,408 204,974 100,167 134,531 n/a

SUMMARY

Statement of the Problem

The etiology of abuse and neglect has been the subject of controversy for decades. Until recently, most explanations of abuse and neglect have relied on single-factor theories, which can be classified as psychological, sociological, or sociocultural. More recently, adapting the work of Belsky and Garbarino, Howze and Kotch proposed an ecological model of abuse and neglect that integrated these three single factor theories with stress and social support into a single etiological model of abuse and neglect. Such a model distinguishes among precipitating, mediating, and predisposing factors that contribute to a maltreatment incident. The model permits a theoretical basis for primary prevention of child abuse and neglect, whereas single-factor theories have emphasized pathology and intervention after an incident of abuse or neglect has occurred. The ecological model not only permits a focus on community-wide prevention, but could identify key characteristics of the mother, the infant, the family, and the stresses and supports in their lives which might help predict those infants at highest risk for maltreatment.

Research Questions or Hypotheses

The purpose of this study was to test the ecological model of abuse and neglect in a cohort of infants judged to be at risk for maltreatment. Specifically, after identifying the



^{*} Indirect included

key predisposing variables that would have to be controlled for, the investigators tested the role of stress in precipitating a report of abuse or neglect, the role of social support in modifying the risk, and the interaction of stress and social support.

Study Design and Methods

The project recruited 1,116 mother-infant pairs between March 1986 and June 1987, of whom 846 were interviewed successfully in their homes 4–8 weeks after the birth of the infant. The lengthy interview (90 minutes) addressed the key factors in the ecological model, namely, individual characteristics of the mother such as her health, mental health, and history of abuse or family violence; the infant's health and temperament; family structure; sociodemographic characteristics, including the mother's report of the quality of her neighborhood; and the mother's parenting beliefs and values. Standardized instruments were selected for measuring these characteristics and stress and social support variables whenever possible.

At about the infant's first birthday, interviewers again returned with a similar interview to provide followup on the mother-infant pair. A total of 459 interviews were completed. Between the time of the first and second interviews, North Carolina's Central Registry of Abuse and Neglect was reviewed bimonthly to identify those subjects who been reported for abuse or neglect.

Analysis of the data relied primarily on logistic regression. Initially, correlations among the variables in each category of the model, and correlations between the predisposing variables and the outcome—reported abuse or neglect—helped to reduce the total number of potential variables to a manageable number whose association with reported maltreatment achieved a *p*-value of 0.05 or less in an uncontrolled test of differences. Similarly, stress and social support variables were also examined, but those with a *p*-value less than or equal to 0.2 were kept. All the variables in each category (mother, infant, family, social, cultural, stress, and social support) were then entered into a separate logistic regression for each of the seven categories with reported maltreatment as the outcome. Nine predisposing, two support, and three stress variables met the criteria for inclusion. The nine predisposing factors were then entered into a single logistic regression with reported maltreatment as the outcome, and four survived. These four variables were used as controls in the final regressions testing the individual and joint roles of the five stress and social support variables in explaining reported maltreatment.

The final tests addressed the relationship of changes from time 1 (T1) to time 2 (T2) in the predisposing factors, and in stress and social support, to reported abuse or neglect. The differences between the T1 and T2 values of the five stress and social support variables were regressed against the outcome using the T1 values of the predisposing factors as controls in one set of regressions. The differences between the T1 and T2 values of the four precipitating factors were used as controls in a second set of regressions.

Study Sample and/or Population

The study population was a cohort of 1,116 mothers and their newborns in hospitals in 42 geographically diverse counties in North Carolina and South Carolina. Subjects were



130

146

selected deliberately to overrepresent infants who were eligible for North Carolina's High Priority Infant Program (HPIP) or its equivalent in South Carolina. Such infants would have had significant medical and/or social problems at birth, such as low birthweight (below 2,000 grams) or low maternal age (less than 14 years). For the purposes of this study, mothers who were between 14 and 17 years of age, inclusive, or whose infants were between 2,000 and 2,499 grams, inclusive, were also recruited. For every four such infants whose mothers agreed to participate, one mother of an otherwise normal infant was recruited. A nurse or social worker, employed by the hospital or health department, described the research project to the mother and asked her if she would like to participate. If the mother agreed, an informed consent was obtained, and participants were referred to a trained interviewer for followup after both the mother and her infant were discharged. Mothers were advised that participation in HPIP was not contingent upon their involvement in the study. The agency employing the nurse or social worker recruiting for the project received \$6.00 for each mother-infant pair enrolled.

Findings

Of 1,116 mothers who signed informed consents, 846 were interviewed at T1 and 459 were interviewed at T2. Of the 846, 86 were reported for child neglect or abuse and neglect. There were no reported cases of abuse only in the first year of life.

The variable screening process reduced 70 predisposing variables to 9 that were significantly associated with reported neglect: Three maternal variables (absence of or rejection by the mother's own mother, education completed, and depression); 1 infant variable (birthweight); 2 family variables (father of infant in the home, number of siblings); 2 social variables (participation in Medicaid or Aid to Families with Dependent Children, satisfaction with neighborhood); and 1 cultural variable (empathy with the infant). When these nine variables were entered into a stepwise logistic regression with reported neglect, only maternal rejection or absence, mother's education, number of siblings, and participation in Aid to Families with Dependent Children or Medicaid were significant at $p \le 0.05$.

The same process yielded two social support variables, the Social Well-Being Index (Donald and Ware, 1982) and the Autonomy and Relatedness Inventory (Schaefer and Edgerton, 1982), and three stress variables, Everyday Stressors (Hall, 1983), and total events and net change from Sarason's Life Experiences Survey (Sarason et al., 1979). When each of these was included in a regression with the four control variables and reported neglect, none was significant. Each of six pairs of the two stress and three social support variables was entered in regressions with their interactions and with reported neglect, however, and one such regression showed significance for total events, autonomy and relatedness, and their interaction.

Finally, in an uncontrolled test of differences, there were significant associations between changes from T1 to T2 in reported and total life events and support from one's personal intimate on the one hand and reported neglect on the other. When controlled either for the four predisposing factors at T1, or for changes in predisposing factors from T1 to T2, however, none of the changes in the stress or social support variables were significant at $p \le 0.05$.



Recommendations

Our findings suggest that the ecological model can be useful in developing strategies for primary prevention of child neglect in the first year of life. Policy development for community-wide intervention should focus on enhancing educational achievement, ameliorating poverty, and providing family planning services to reduce the conditions that predispose to neglect. The fact that the mother's perception of her relationship with her own mother is significantly associated with a neglect report suggests that such a strategy may have benefits into the next generation.

Life events are also associated with the reporting of neglect in this low-income population, as is the support of a personal intimate. It is unlikely, however, that public agencies can influence the frequency with which positive events occur in people's lives. They may encourage the prospective mother to identify and enhance supportive relationships with the individual she designates as her closest intimate. It does not seem, from these data, that strategies to reduce maltreatment purely through prevention of medical problems will be effective in the presence of those factors identified here as overwhelmingly predictive of neglect reports. Rather, health and social agencies may identify those at risk by asking four simple questions regarding educational achievement, participation in Aid to Families with Dependent Children or Medicaid, number of siblings in the home, and history of maternal absence or rejection.

It is easier to make recommendations about future research. In our view, the experiences of families subsequent to an infant's first year of life are critical to understanding child neglect. Indeed, new insights about child abuse may derive from case reports which occur in later years of life. Similarly, the effects of the neglect and abuse (if any) on the child's health, mental health, and school performance remain to be explored. Finally, a similar study, using a random sample of the entire population of newborns rather than a sample of high-risk newborns, may result in different conclusions about the usefulness of the ecological model and its implications for the primary prevention of abuse and neglect in the general population.

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Abstracts

None to date.

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IMPROVING AUDITORY TESTING OF MULTIHANDICAPPED CHILDREN

GRANTEE

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PROJECT NUMBER

MCJ-390548

REPORT NUMBER

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PROJECT PERIOD

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COS	515*
	Awarded
	Requested

Year 1	Year 2	Year 3	Year 4	Year
68,942	68,702	n/a	n/a	n/a
81,434	75,668	n/a	n/a	n/a

SUMMARY

Statement of the Problem

With the current emphasis on early intervention and interdisciplinary team assessment, audiologists are now being consulted about the prognosis for improvement, habilitation/educational programming, and the functional status of hearing among children with handicaps. Audiological assessment of severely and profoundly multihandicapped children is particularly challenging, as they are unable to respond to auditory stimuli in the same manner as their nonhandicapped peers, due to structural, muscular, central nervous system, and cognitive disabilities.

Traditional hearing tests used with these individuals are those employed in testing infants who cannot be trained to respond in a specific manner, such as turning toward the sound source, dropping a block, or raising a hand. These tests include behavioral observation audiometry, which documents any response to sound, and physiological procedures, which do not require volitional responses. Interpretation of the results is generally based on the auditory development of nonhandicapped children. Application of these tests to children with severe and profound multihandicaps, however, has created a number of questions about the reliability and validity of the test procedures. In addition, evidence exists that these children may not follow the same developmental progression in auditory maturity as do their nonhandicapped peers.



^{*} Indirect included

Research Questions or Hypotheses

The goals of this study were to evaluate and improve the auditory testing techniques used with severely and profoundly multihandicapped children, and to longitudinally investigate the auditory development of these children.

Study Design and Methods

Subjects were tested weekly, using behavioral observation audiometry, visual response audiometry, auditory brainstem response, the noise-tone difference test, or a combination of tests. The results of the weekly hearing tests were used to identify areas for procedural modifications and to test those modifications.

The weekly test results for behavioral observation audiometry, visual response audiometry, and noise-tone difference were included with information on the child's chronological age, overall functioning age, disability onset, visual status, and daily auditory behavior to build two auditory developmental profiles—one based on developmental age, and the other based on the developmental stage of maturity. This information was post hoc, gathered from archived audiological files, psychological profiles, and medical, educational, and therapy reports. In addition, behavioral observation audiometry results for three nonhandicapped children were obtained in 10 testing sessions while the children were between the ages of 2 weeks and 13 months, for comparison with severely and profoundly multihandicapped children. The profile based on developmental stages was found to be the most appropriate for use with severely handicapped clients and, thus, was used throughout the hypothesis testing.

Study Sample and/or Population

The study population consisted of all severely and profoundly multihandicapped individuals referred to the Kent State University Speech and Hearing Clinic between 1977 and 1988 who did not respond to traditional (volitional) behavioral techniques during auditory testing. No client was excluded on the basis of chronological age, gender, race, or specific disability type.

Archival records for 323 clients were used in some part of the study. Evidence of developmental testing, audiological testing involving behavioral observation audiometry, visual reinforcement audiometry, auditory brainstem response audiometry, and/or the noise-difference test during immittance audiometry were required for inclusion. The actual number of clients involved in each subcomponent of the investigation varied due to occasional missing information. The records for these 323 children produced results from 785 testing sessions. In additional to psychological and audiometric information, medical information was gathered on etiology, a list of physical impairments, current medications, and onset of disability (prenatal, perinatal, or postnatal). None of the 323 clients in the target population were ambulatory or were able to use verbal or gestural communication to indicate responses to auditory stimuli. All had been diagnosed by a physician and licensed psychologist as having severe to profound motor and mental impairments.

The chronological ages of the clients ranged between approximately 4 months and 21 years, with an average age of 8 years. Developmental ages ranged from 2 weeks to



approximately 24 months, with an average of 2 months. Most of the clients resided at a local facility engaged in providing living, habilitative, and medical services for the severely and profoundly involved. Others, however, lived with their natural parents or in foster homes.

Findings

The minimum response levels were compared for behavioral observation audiometry, auditory brainstem response, noise-tone difference, and visual response audiometry. Although auditory brainstem response was considered the single best test for ruling out moderate-severe-profound, bilateral, sensorineural hearing losses, a seriespositive test battery was advocated. A test battery was considered important since test results were sensitive to the type of disability/etiology presented by the client. A factor analysis showed that the presence of cerebral palsy and a history of encephalitis were associated with results from behavioral observation audiometry, degenerative and structural central nervous system abnormalities were associated with auditory brainstem response, and middle ear problems were associated with noise-tone difference results. It was further concluded that the test battery should begin with visual response audiometry followed by behavioral observation audiometry. Both of these tests provide developmental as well as hearing sensitivity information. The third test should be the noise-tone difference (obtained during immittance testing), followed by auditory brainstem response (suggested as a final test because of the expense involved and the sedation that might be required).

The efficacy of the series-positive test battery approach depends upon test protocols that are valid, reliable, and conservative. To meet these criteria, behavioral observation audiometry testing techniques were modified to decrease the judges' bias, improve ease of scoring, and reduce the number of professionals required in the testing process. The number of audiologists involved in actual testing was reduced to one; the number of behaviors to be scored was reduced from 23 to 11.

Implementation of a training program to observe responses to sound permitted the use of nonaudiologists as judges and increased reliability of the judges individually and as a group. Furthermore, the number of judges was reduced from five to two. Modifications were also made in the criteria for predicting the middle latency response. Originally, alpha levels of .05 and .01 were used for all *t* tests, whereas current procedures involve the use of .05 and .01 only during comparison of the highest intensities (90–70 decibels). Alpha levels of .1 and .05 at levels of 70–50 and 50–30 decibels are now used since the chances of a child being deaf but responding to sounds presented at 50 decibels hearing level (HL) or better are still less than 1 percent. The fact that the children were tested unsedated and that their neurological disabilities affected the auditory brainstem response tracings did necessitate major modifications in auditory brainstem response procedures. The low-frequency cutoff was increased to 300 Hz, about twice the normal value used. A total of 8,192 samples were recorded at each intensity to improve the signal-to-noise ratio, and results were printed out as single and overlapped tracings for each stimulus intensity.

Two software packages were developed to aid in auditory brainstem response testing of severely and profoundly multihandicapped children. The first was used to



digitally filter individual tracings using fast Fourier transform (FFT) analysis to reject low and high frequency noise without introducing phase distortion. Auditory brainstem response testing of 10 normal-hearing adult subjects and 128 severely and profoundly multihandicapped clients was used to validate the procedure. Middle latency responses and the 40-Hz potentials were tested as alternatives to auditory brainstem response testing but proved unsatisfactory. The middle latency response was adversely affected by low frequency electroencephalographic activity, which was often abnormal and large in neurologically impaired children and could not be filtered as could the auditory brainstem response. The 40-Hz potential is highly dependent upon central nervous system maturation, which again is highly variable and questionable among severely and profoundly multihandicapped children and adolescents.

The second software package involved the objective analysis of auditory brainstem response traces. The correlations between visual and computer-driven analyses of noise tracings and associated variances were reviewed. The computerized objective analysis of auditory brainstem response tracings was found to concur with visual readings in 100 percent of the hearing adults and in 74 percent of the handicapped children. Agreement rose to 87 percent when a range of \pm 20 decibels was accepted. Although scoring bias was found for auditory brainstem response visual analysis, it was concluded that using both visual and objective evaluation of tracings would be the most effective way of estimating auditory brainstem response threshold.

Comparisons between noise-tone difference results using 220-Hz versus 660-Hz probe tones were made for subjects with near-normal hearing, moderate-to-severe hearing losses, and profound hearing losses. The 660-Hz probe tone was able to elicit a higher percentage of acoustic reflex thresholds than the 220-Hz probe, but there was no evidence for noise-tone difference scores to predict a greater number of subjects having normal sensitivity. Therefore, the traditional 220-Hz probe tone was used throughout the project.

The second goal of the investigation was to obtain developmental information regarding auditory maturity. This goal was undertaken to determine whether severely and profoundly multihandicapped children and nonhandicapped children follow the same developmental paths, to isolate some of the variables affecting the development of functional hearing in handicapped individuals, and to investigate the use of the preceding information in making prognostic and habilitative decisions. Developmental profiles were built, based upon the age at which a behavior should appear (developmental age) and the complexity of the response (developmental stage). Severely and profoundly multihandicapped children did not follow the same progressions of development as did nonhandicapped children, regardless of the profile used. The behaviors salient to profile construction differed, as did the manner of progression along the profiles. Infants without handicaps progressed linearly, completing the progression in about 7 months, whereas the development of the handicapped children was punctuated by advancement, regression, and plateaus and may not have completed the progression in 21 years. Salient information leading to a determination of auditory maturity included knowledge of the number of body startles, head/limb jerks, increased motion, and localization changes in response to sound during behavioral observation audiometry;



knowledge of ability to condition to visual response audiometry; and social/educational responses to sound.

The developmental stage profile was considerably more appropriate for tracing the auditory changes occurring in the multihandicapped children than was the age-based profile. The developmental stage profile was therefore used to test the hypotheses in the remainder of the longitudinal study. The pattern of auditory development was affected by the individual characteristics of the multihandicapped child (i.e., the type and degree of hearing loss, the time of disability onset, and visual ability).

The level of auditory development did not necessarily coincide with a high or low overall functioning age. The meaningfulness of sound was approached through responses to visual response audiometry, response decrement, and attainment of the comprehension stage of development. Conditioning to sound through visual response audiometry depended upon having no more than a severe functional visual loss, and was found at an earlier overall functioning age in severely and profoundly multihandicapped children than would be expected among children without handicaps. Response decrement did not appear to be associated with developmental age (or stage) for nonhandicapped or multihandicapped clients. This latter finding might have been influenced by the fact that the behavioral observation audiometry paradigm was constructed to minimize response decrement.

Recommendations

The popular use of behavioral observation audiometry, auditory brainstem response, noise-tone difference, and visual response audiometry, as used with nonhandicapped infants and young children, requires modifications in the way the tests are performed and in the way results are interpreted when applied to severely and profoundly multihandicapped individuals. Therefore, the following recommendations are made for adjusting the testing procedures:

- 1. A series-positive test battery approach should be used.
- 2. The sequence of testing should be visual response audiometry, behavioral observation audiometry, noise-tone difference, auditory brainstem response.
- 3. Visual response audiometry should always be conducted to determine responsiveness to sound, regardless of visual impairment. The presence of light versus dark discrimination may be enough for the test to be successful.
- 4. Behavioral observation audiometry should be conducted so that the judges are unaware of the sound being presented in order to reduce observer bias.
- 5. Behavioral observation audiometry judges should be trained in scoring and the behavioral changes they may see. If the judges are trained, they need not be audiologists and may consist of a team of two professionals. If they are not trained, at least five judges are necessary to obtain similar results.
- 6. The middle latency responses obtained from each of the judges should be compared, and the better of the two accepted as the child's middle latency response.
- 7. Behavioral observation audiometry should encompass both the certainty scores and the type of behavioral change made.



- 8. Auditory brainstem response data should be evaluated objectively and visually to reduce effects of scoring bias.
- 9. Auditory brainstem response should utilize a higher frequency cutoff and more samples than are normally used.

The following recommendations are made for interpretation of test results:

- 1. Additional information regarding daily responses to sound, medication, disability type, etiology and onset of disability, and visual ability is necessary to aid in interpretation of results.
- 2. The above information should be used together with visual response audiometry results and knowledge of behavioral changes in response to sound in order to implement the developmental stage profile in describing the child's current auditory maturity status.
- 3. Developmental ages and stages based on behavioral changes in response to auditory stimuli in nonhandicapped children should not be used to measure or predict sound usefulness in children with severe and profound multihandicaps.

Further research needs to be conducted in field testing the hearing test procedures to refine them and make them usable in nonuniversity settings. The developmental profile was based upon ad hoc data. Additional controlled studies are necessary to determine whether or not the results are applicable and may be used as prognostic indicators of future useful hearing. Previous experience with auditory training and severely and profoundly multihandicapped individuals was very successful in many cases. It would be advantageous to investigate the usefulness of the profile in a field site and to determine whether training/intervention could make a difference in reducing the discrepancies between the nonhandicapped and multihandicapped profiles.

Publications

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Abstracts

None to date.

Presentations

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IMPROVING AUDITORY TESTING OF MULTIHANDICAPPED CHILDREN

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Gans D. What do we do with this amount of hearing? or Audiological strategies for teaching. Seminar presented at Functional Audiological Strategies for Students with Multiple Disabilities conference, New England Center for Deaf-Blind Services, Boston, MA, 1988.

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PREDICTION OF OUTCOME OF EARLY INTERVENTION IN FAILURE TO THRIVE

GRANTEE

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Year 1 Year 2 Year 3 Year 4 91,958 72,014 65,511 no cost

extension

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no cost n/a

Year 5

n/a

extension

SUMMARY

Statement of the Problem

Nonorganic failure to thrive (NOFTT) is a pediatric problem that occurs frequently, can be reliably detected during infancy, and is associated with a high degree of psychological risk. However, the specific areas of psychological development most vulnerable to the effects of NOFTT and associated risk factors have not been well documented. One of the most salient but, as yet, unanswered questions concerns the processes that affect the long-term socioemotional outcomes of infants with nonorganic failure to thrive. Although physical symptoms and malnutrition associated with NOFTT generally remit with medical treatment, psychological symptoms are identified long past the point of diagnosis and early treatment.

Moreover, research has not yet identified the factors that influence positive versus negative health and psychological outcomes among children with early histories of NOFTT who received pediatric and psychological intervention as infants. For this reason, clinical practitioners do not have an adequate base of knowledge to guide their decisions concerning psychosocial treatment and long-term planning.

This study was designed to address the need for controlled studies of psychological outcome in preschool children with early histories of nonorganic failure to thrive, using a comprehensive assessment approach. Nonorganic failure to thrive occurs among children with a wide range of family, ethnic, and socioeconomic backgrounds.



^{*} Indirect included

Research Questions or Hypotheses

The purpose of this study was to conduct a controlled, prospective followup of children with early histories of NOFTT who received early intervention as infants; the study included a comparison group of physically healthy children from infancy to 48 months of age.

The study's two primary objectives were to:

- Conduct a comprehensive assessment of the psychological outcomes of a cohort of children ages 42 and 48 months, who were initially hospitalized for NOFTT as young infants and who received time-limited early intervention following hospitalization. The outcome of this group is compared with that of physically healthy children from similar socioeconomic circumstances.
- 2. Identify factors that predict the psychological outcomes of preschool children with NOFTT who received comprehensive pediatric and psychosocial intervention as infants.

Specific hypotheses included the following: (1) Children with early histories of NOFTT will demonstrate greater frequencies of psychological symptoms and less adaptive psychological development than physically healthy children from comparable socioeconomic backgrounds; and (2) quality of family functioning will predict behavioral symptoms.

Study Design and Methods

Predictor variables included security of attachment as assessed by the Ainsworth Strange Situation Procedure, and quality of family relationships as assessed by the Family Environment Scale. Outcome measures included (1) psychological competence based on home observation, (2) experiment-based measures of ego control and ego resiliency, family functioning, family environment, and behavioral symptoms, as measured by the Child Behavior Checklist, and (3) a measure of problem solving.

The comprehensive outcome assessment used data gathered from multiple observations, starting at 12 months of age and continuing through 48 months. In addition to the primary or target measure pertaining directly to socioeconomic development, children's cognitive development and physical growth were assessed.

Study Sample and/or Population

The sample of children with early histories of NOFTT was recruited from six hospitals in the Cleveland area. Children (N=48) were between 1 and 9 months of age, met objective criteria for growth deficiency, and had no primary organic or constitutional etiologies for their growth deficiency based on comprehensive pediatric evaluation and physical diagnostic tests. Physically healthy and normally growing children (N=47) in the comparison group were recruited from similar health care facilities and geographic locations as the NOFTT sample. This comparison group was added to control for variables known to affect the long-term psychological outcomes of children with NOFTT. These include child characteristics (age, gender, race, birth order, prematurity), maternal characteristics (maternal education and age), and family characteristics (family size, income, and constellation). The majority of the overall sample (N=78) came from



economically disadvantaged families who are recipients of Aid to Families with Dependent Children. The racially heterogeneous sample included 64 African-American children and 31 white children.

Findings

Our first set of analyses concerned differences in psychological and family functioning between children with early histories of NOFFT and the comparison group. As predicted, children in the comparison group demonstrated higher levels of ego control and ego resiliency than children with early histories of NOFFT. These findings were primarily based on children's response to structured measures and were not found on home observations.

On the other hand, children with early histories of NOFFT had a higher frequency of behavioral problems on the Child Behavior Checklist than children in the comparison group. However, no differences were found in the number of children in each group who scored in t¹ 2 clinical range on total behavioral problems. Internalizing and externalizing symptoms were also comparable in the two groups.

A third set of comparisons concerned the differences in family functioning between the NOFFT and comparison group samples at study intake and at age 4. Families of infants with NOFFT demonstrated less optimal relationships as indicated by lower standard scores on the Family Relationships Inventory than the comparison group at study intake and age 4. The groups did not differ in the frequency of housing and family structured changes from intake to followup at age 4.

Our final set of results concerned the prediction of personality development, behavioral symptoms, and family functioning within the sample of children with early histories of NOFFT. Type of time-limited intervention (family-centered, parent-centered, or advocacy) did not have significant effects on any of the psychological outcomes or family functioning variables. However, several individual difference variables emerged as significant predictors of psychological and health outcomes within the sample of children with early histories of NOFFT. For example, children rated as securely attached at 12 months of age were rated as less rigid under stress, as having high standards of performance for self, as more competent and skillful, and as more creative than insecurely attached children. Securely attached children were less likely to be rehospitalized than insecurely attached children.

Finally, quality of family relationships at age 3 predicted behavioral symptoms measured at age 4. More adaptive family relationships were associated with a lower frequency of behavioral symptoms. Nutritional status intake at subsequent followup did not predict behavioral symptoms.

Recommendations

Our findings document continuing psychological risk to children with early histories of NOFFT who were hospitalized for this condition and received time-limited intervention as infants. In particular, children with early histories of NOFFT demonstrated more behavior symptoms, and less adequate abilities to contain impulses, delay gratification, or change their behavior in response to novel situations.



144

160

A primary contribution of this study is the identification of factors that may protect preschool children with early histories of NOFFT from developing behavioral problems. Quality of family relationships was associated with fewer symptoms, and secure attachment at 12 months of age was associated with more competent behavior at age 3.

Our findings suggest that pediatricians should continue to monitor the psychological adjustment of children with early histories of NOFFT, especially those with dysfunctional families. Additional studies are needed to determine whether children with early histories of NOFFT who demonstrate problematic behavioral control as preschoolers continue to demonstrate problems as school-age children. Finally, it would be instructive to assess the efficacy of interventions tailored to the specific etiology (e.g., maternal relationship deficits, family dysfunction) of NOFFT. The efficacy of interventions designed to enhance the parenting abilities and reduce the level of behavioral problems in preschool children with early histories of NOFFT should be assessed in controlled studies.

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161
COMPLETED PROJECTS 1989, 1990, AND 1991



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Abstracts

None to date.

Presentations

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Drotar D. Invited keynote address: Advances in failure to thrive research: Implications for practice. Presented at the Conference on Current Trends in Failure-to-Thrive Management, LaRibida Children's Hospital and Research Center, Chicago, IL, September 1990.

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146

ADENOIDECTOMY, EUSTACHIAN TUBE FUNCTION AND OTITIS MEDIA

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Costs*	
Awarded	

Year 1 Year 2 Year 3 Year 4 Year 5 143,040 152,910 175,998 198,260 n/a 173,941 185,939 198,954 214,623 n/a

Requested

SUMMARY

Statement of the Problem

Otitis media is the most common illness for which children receive medical care in the United States, and adenoidectomy (with or without tonsillectomy) is the most common major surgical procedure in children to prevent otitis media. Now that studies showing the efficacy of adenoidectomy have been completed, even more children will be subjected to this surgical treatment. However, it is not known which children will benefit from adenoidectomy.

Research Questions or Hypotheses

This study was designed to examine the effect of adenoidectomy on eustachian tube function (ETF) and to relate these findings to the efficacy of the operation in reducing morbidity from otitis media. If some children were found to have significantly less morbidity from otitis media following adenoidectomy, and if the findings of ETF tests could identify such patients, it would be possible to separate those children who may benefit from adenoid surgery from those who will not.

Study Design and Methods

This was a prospective, randomized, controlled clinical trial of children who had tympanostomy tubes inserted in the previous 6 months due to chronic otitis media with effusion, or frequently recurrent acute otitis media, or both. Children ages 3–12 years



^{*} Indirect included

were randomly assigned to adenoidectomy or nonsurgical control groups. Eustachian tube function tests—consisting of the modified inflation-deflation test, forced response test, and eustachian tube compliance—were performed before randomization and every other month after randomization, even when an upper respiratory tract infection supervened. The results of these function tests were to be related to important outcome measures such as episodes and duration of middle ear disease, number of subsequent myringotomy and tympanostomy tube procedures, hearing, and complications and sequelae of the disease and the surgery. Each child was observed/treated monthly for 1 year from the time both tubes extruded or became nonfunctional. Independent variables assessed in addition to eustachian tube function were age, nasal obstruction, history of past ear disease (recurrent or chronic, or both), number of prior tympanostomy tube procedures, allergy, gender, and race.

Study Sample and/or Population

A total of 81 subjects were entered in the study between March 1985 and May 1989. Twenty subjects (24.7 percent) were 3 years of age, 57 subjects (70.4 percent) were 4–8 years, and 4 subjects (4.9 percent) were 9–12 years. Forty-six subjects (56.8 percent) were male, 73 (90.1 percent) were white, 7 (8.6 percent) were black, and 1 (1.2 percent) was American Indian. The tympanostomy tubes present at entry were the first set of tulies for 31 subjects (38.3 percent), the second set for 32 subjects (39.5 percent), the third set for 15 subjects (19.5 percent), and the fourth or more for 3 subjects (3.7 percent). Tubes were inserted because of persistent otitis media with effusion in 54 subjects (66.7 percent), for recurrent acute otitis media in 18 subjects (22.2 percent), and for both reasons in 8 subjects (9.9 percent). The reason for insertion was unknown in one subject.

Findings

A total of 74 subjects completed prerandomization testing and were randomly assigned to receive either adenoidectomy or no surgery. Analyses of ETF tests revealed no significant improvement in any parameter in either the surgical or control group between prerandomization and 2 or 6 months after randomization. No difference was observed between the two treatment groups in the degree of deterioration of ETF when subjects had upper respiratory infection symptoms compared with times when they were without upper respiratory infection. Among those followed for 1 year after the tubes became nonfunctional, more subjects in the surgical group had middle ear effusion less than 10 percent of the time than did subjects in the control group ($X^2 = 6.41$, p < 0.01), although there was no difference between the two groups in numbers of episodes of acute otitis media postoperatively.

Recommendations

Since the results of this study showed that a preoperative assessment of ETF, as currently tested, is not predictive of success or failure of adenoidectomy in preventing otitis media with effusion or acute otitis media, future research should be directed toward improved assessment of ETF and the design of future clinical trials that will use the new

164



test(s). One such method, magnetic resonance imaging, is currently in the development stage.

PUBLICATIONS

Articles and Chapters

None to date.

Abstracts

None to date.

Presentations

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COHORT STUDY OF UTERINE CONTRACTIONS IN BLACK WOMEN

GRANTEE

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Costs*
Awarded

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

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 n/a
 n/a

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 n/a
 n/a

SUMMARY

Statement of the Problem

One of six inner-city black babies is born prematurely. Most such births result from preterm labor or preterm rupture of the membranes. It is widely thought that increased baseline uterine activity may predispose women to both these conditions. However, very little information is available about contraction frequency, intensity, and duration during the second and third trimesters of pregnancy prior to onset of labor. Recent technical advances in the design of tocodynamometers now make research on this topic possible.

Research Questions or Hypotheses

The overall objectives of this study were to describe uterine activity in inner-city black women during the second and third trimesters of pregnancy and to assess the effects of physical activity, smoking, and other maternal factors on contraction characteristics.

Study Design and Methods

Participants wore ambulatory tocodynamometers (Termguard) for 72 consecutive hours at each of three gestational ages, each 4 weeks apart (weeks 22–25, 26–29, 30–33). During these periods, participants completed checksheet diaries on physical activity, smoking, and emotional state. Their caloric expenditure was estimated with a motion

^{*} Indirect included/† Not available at the time of publication.

sensor (Caltrac). All tocodynamometry data were interpreted by one observer who was blinded to study hypotheses, and who exhibited excellent intraobserver reliability.

Values for all individuals were combined to create summary point and interval estimates for each contraction characteristic for each of the three pregnancy outcome groups (full-term, preterm labor, and other preterm delivery). Summary measures of contraction frequency, duration, and intensity were also assessed for specified time intervals within each gestational period, including each 24-hour period, as well as for each hour and each 12 hour-period, for an averaged 24-hour day. These time-specific summary measures were plotted against time and inspected for gestational period and diurnal trends.

In the full-term group, a repeated measures analysis of variance was performed on each measure of contraction frequency, intensity, and duration, to determine whether there was statistically significant variation between gestational periods, days, and time of day for any of these measures. In addition, cosine analysis using a repeat period of 24 hours was applied to each individual's 72 hours of hourly contraction rates to determine whether there were significant diurnal rhythms.

To assess whether uterine activity differed among women according to factors such as smoking status and parity, Student's *t* test and a Wilcoxon-Mann-Whitney test were performed at each gestational age period for each measure of uterine contraction. Additionally, by incorporating variables that define these subgroups into the repeated measures model discussed previously, a multivariate approach was used to assess subgroup level differences.

Multiple linear regression modeling was used to explore the hypothesis of a relationship between the continuous variables such as maternal weight and caloric expenditure estimate and uterine contraction activity. Since the distribution of the contraction characteristics (frequency, intensity, and duration) was skewed, the natural logarithms (which were normally distributed) were used for analysis. Piecewise regression was performed to evaluate the issue of whether there was a maternal weight below which there was no weight effect on contraction frequency.

Study Sample and/or Population

A total of 89 inner-city black women without major medical risks for preterm labor participated in this prospective cohort study. Eighty-one participants had term uncomplicated pregnancies, 5 developed preterm labor, and 3 delivered prior to term because of medical complications including preterm rupture of the membranes.

Findings

Following are the major findings from this study:

- 1. Mean hourly uterine contraction frequency and intensity increased significantly with advancing gestational age. Contraction duration did not change significantly among gestational age periods studied.
- Maternal weight had a profound effect on uterine activity with an inverse linear correlation between maternal weight and the natural logarithm of contraction rate. This effect was apparent for women weighing more than 112 percent of



- ideal weight for height and gestational age. It is likely that this finding reflects technical difficulty in monitoring increasingly obese women, but a physiologic difference cannot be excluded.
- 3. During the second and third gestational age periods studied, there was a diurnal pattern to contraction frequency with peak uterine activity occurring during the night. Although this pattern was present for women who were not sexually active on monitoring days, it was significantly more pronounced for women who had coitus during evening or night hours.
- 4. Maternal age, parity, smoking, and physical activity level estimated by caloric expenditure or composite index based on diary information had no significant effect on uterine contraction characteristics.
- 5. Descriptive data on contraction frequency and other characteristics were also provided for the five women who experienced preterm labor and the three women who had indicated preterm deliveries without preterm labor. Their contraction characteristics were similar to those of the 81 women who delivered at term, although the small sample sizes preclude any statistical or clinical evaluation.

Recommendations

This study provides background information defining the limits of normal prelabor contractions in ambulatory, low-risk women. Gestational age, maternal weight, time of day, and selected physical activities have been shown to impact on contraction frequency. While not immediately applicable to health care service, this information is useful to professionals using home uterine activity monitoring for high-risk patients and to researchers interested in the impact of maternal activities during pregnancy.

Specific suggestions for further research include:

- 1. Further standardization of interpretation of contraction monitoring data:
- 2. Prospective evaluation of the threshold level above which there is a maternal weight effect on uterine contraction rate, including the impact of changing the tocodynamometer baseline pressure; and
- 3. Assessment of the impact of specific physical activities on uterine contraction rates in more controlled settings.

PUBLICATIONS

Articles and Chapters

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Abstracts

None to date.

Presentations

None to date.

168



DIAGNOSIS RELATED GROUPS (DRGS) AND THEIR IMPACT ON PERINATAL REGIONALIZATION

GRANTEE

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PROIECT NUMBER

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NTIS NUMBER

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PROIECT PERIOD

Awarded

Requested

05/01/87-09/30/88

Costs*

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 209,258
 272,537
 137,483
 n/a
 n/a

 209,258
 272,537
 137,483
 n/a
 n/a

SUMMARY

Statement of the Problem

Although neonatal care and high risk obstetric care currently are not under the Medicare Prospective Payment System to any meaningful degree, the diagnostic related group (DRG) methodology used in the system has created weights and payments which could be applied to these cases. As individual States consider moving toward Medicaid or all payor systems of reimbursement that use DRG-type mechanisms (already implemented in 16 States) and as Congress and State insurance commissions examine broad approaches to cost-containment, widespread implementation of a diagnosis-based reimbursement system may become a reality in the 1990s.

Diagnosis related groups were created with the assumption that reimbursement based on averages would not result in dramatic losses for an entire diagnostic related group because cases would balance out. Unfortunately, this assumption holds that the case distribution within DRGs is similar across hospitals. The premise of regionalized perinatal care dictates that high-risk cases be referred only to perinatal centers. Research and analysis on the impact of the DRG system and the existing categorization are important to ensure that perinatal hospitals that receive a disproportionate share of high-risk cases would not be adversely affected.

Research Questions or Hypotheses

This study was designed to address three major research questions:

1. How widespread and serious are the financial implications of diagnostic related groups for perinatal care?



^{*} Indirect included

- 2. What, specifically, is causing the problem?
- 3. What changes can be introduced into a case-mix method of reimbursement that can solve the problems identified?

Study Design and Methods

This study compared a group of perinatal centers to a group of hospitals that do not provide high-risk services. The overall design of the study was cross-sectional in nature, comparing two groups of hospitals, where primary questions are addressed at the facility level. In other words, the central questions of the study, focusing primarily on differences in net gain and case-mix across two hospital groups, were addressed by combining and then comparing data from two groups of hospitals.

This study identified the net loss or gain expected under Medicare reimbursement by studying the difference in cost and expected reimbursement for care across perinatal centers and a comparison group of hospitals. To address the first study question, the financial impact of the Medicare model of reimbursement on a group of tertiary perinatal centers compared to other nontertiary hospitals was examined. Each obstetric and neonatal DRG was assessed separately.

For the diagnostic related groups where losses were identified, analyses were aimed at assessing the sources of the losses and whether these differences were due to casemix. The analyses aimed at exploring the difference in case-mix used a variety of casemix measures, including length of stay, diagnosis, birthweight, and discharge disposition.

The third analysis was aimed at improving the case-mix grouping and reimbursement. The analysis had three goals: Creation of a schema that did not result in reimbursement losses; results demonstrating less variability within diagnostic related groups, and equitable payment across both groups of hospitals.

Study Sample and/or Population

The two groups of hospitals compared were hospital perinatal centers and hospitals that did not offer high-risk perinatal services. By analyzing the American Hospital Association data tapes and a survey of State MCH directors, the study team identified the tertiary perinatal care centers operating in 1985. To remain on the perinatal center list (or to be added), hospitals had to, at a minimum, provide assisted ventilation, retain all nonsurgical cases (no matter how premature or small), and have a neonatologist on staff.

The resulting list included 385 tertiary perinatal centers (excluding military and children's hospitals) and 3,691 other hospitals. After a review of the distributions of rural and urban hospitals for each group, and the distribution of births, it was decided that the sample would be drawn only from those urban hospitals with 900 births or more. These two variables reduced the tertiary perinatal center group from 385 to 361. The comparison group dropped from 3,691 to 685 (946 hospitals had less than 900 births, and 2,060 hospitals were in nonurban areas).

The universe of urban hospitals with more than 900 births was then stratified according to size and teaching intensity. This approach was selected to eliminate the confounding effect of size and teaching intensity in the data analysis.



The final study sample included 28 tertiary facilities and 22 nontertiary facilities. Due to empty cells, the financial and case-mix analyses were performed using 24 tertiary hospitals in cells corresponding to the 22 nontertiary hospitals.

Findings

1. Following are the neonatal findings:

Average total gain per hospital was used to measure the impact of the Medicare model of reimbursement on tertiary perinatal centers compared to nontertiary hospitals. We examined this measure for each neonatal DRG and also examined the net effect of all of these together. Our findings reveal that for very high risk diagnostic related groups, tertiary centers would lose substantial sums if reimbursed using this approach. On average, high-risk DRGs would account for losses in excess of three-quarters of a million dollars per hospital. Surprisingly, the study also found that the other diagnostic related groups (those for well infants and less seriously sick infants) result in gains of roughly \$2.5 million, with a net gain across all neonatal DRGs of \$1.7 million. Nontertiary centers demonstrated a net gain for all neonatal cases, even those in the highest risk categories.

The finding of the case-mix analyses revealed that all very high risk neonatal diagnostic related groups do not control for case-mix. There were large differences in average and geometric mean length of stay, percentage of outliers, and birthweight. Two diagnostic related groups that include infants who are not of normal health, but do not include the sickest infants, did not reveal evidence of case-mix differences. There were also no differences for normal infants.

The DRG grouping schema was compared to the case-mix grouping schema developed by the National Association of Children's Hospitals and Related Institutions, and we established that the explanatory power of the Children's Diagnostic Related Groups (CDRG, version 5.0) was .49 for length of stay compared to .23 for DRGs. The DRG system could be dramatically improved. However, the analyses also revealed that the CDRG grouping schema resulted in a large number of small cells which could negatively affect the operation of the averaging principle in reimbursement.

To address this problem, we sought an alternative approach to controlling for casemix. The schema that was designed and analyzed used a transformed curvilinear function in addition to diagnostic related groups. This approach assumes that cases would be grouped by DRG and would receive an adjusted payment based upon birthweight. We found that the explanatory power of this model was .46 and compared favorably with the CDRG's R_2 of .49 for length of stay. Other models were also investigated, but we concluded that this approach is superior to the CDRG approach, which divides neonatal cases into a large number of small groups.

The final set of neonatal analyses sought to identify the financial impact of using this revised case-mix schema on the study hospitals. We examined the total losses and gains across each group of hospitals under three different scenarios: (1) DRGs as currently reimbursed, (2) their performance if the weights are adjusted, and (3) their performance if the weights are adjusted and the payments are adjusted using birthweight. The findings revealed that there are inequities in both underpayment and overpayment under the existing system. Overpayment across all neonatal DRGs for the 50 hospitals would have



been more than \$101 million. When the weights are adjusted, this amount drops to \$38.4 million.

Finally, when the birthweight adjustment factor is added, the overpayment drops to \$6.6 million. Even more important, however, are the impacts on tertiary and nontertiary facilities. While the original DRG system results in underpayment of more than \$4,000 for the highest risk neonatal cases in tertiary hospitals and an overpayment of more than \$6,000, the revised implementation of a birthweight adjustment factor eliminates the inequity by both eliminating underpayment in the tertiary group and reducing overpayment in the nontertiary group. This result cannot be achieved by merely recalibrating the weights. This analysis revealed in a very stark way that the adjustment of the weights alone, when case-mix is not controlled, is of very limited value.

The fact that tertiary hospitals would profit from the application of current categories is an artifact of the payment weight. Gains do counterbalance losses-indeed, they more than compensate for them-and hospitals would not be faced with the need to withdraw specialized services. However, this outcome is more or less a random occurrence and does not stem from homogeneity with DRGs.

Following are the obstetric findings:

The financial impact analysis revealed that both tertiary and nontertiary hospitals would face losses over all the obstetric cases. Of the 13 obstetric DRGs studied (2 of the groups had so few cases they could not be studied), the differences in losses were significant in only 2 of the groups. In one, the case-mix was significantly different; in the other, the difference was significant in some measures and not in others.

The case-mix analyses included a large number of measures and were performed even for DRGs where there were no losses, in an attempt to identify whether the obstetric DRGs as a schema were poorly constructed. Of 13 DRGs, only 4 were identified as having case-mix differences. In each of these, the difference in average length of stay for the two hospital groups was statistically significant. However, in none of these did the difference exceed 1 day. Although, proportionally, the difference was as high as 29 percent, we question whether revision of the schema could be justified based on such findings.

Further analysis using regression models in examining the explanatory power of the obstetric grouping schema established that the schema performs better than the CDRG schema or the birthweight-adjusted schema which we recommend as an improvement in neonatal DRGs.

Recommendations

The magnitude of the profitability of some of the DRGs may provide incentives for the proliferation of more intensive services in nontertiary settings; these hospitals might then be tempted to "skim the cream" by retaining less seriously sick cases across all DRGs and referring the more seriously ill cases within each DRG. While the competitive environment in health care means competition for patients, the reimbursement parameters now in place are designed to intensify the situation.

Since volume and some admixture of less severely ill patients play a crucial role in balancing profitability, a change in referral patterns would threaten tertiary care facilities.



Regionalization can be threatened as easily by inequities in one direction as another. Ultimately, only appropriate case-mix adjustment—and appropriate weighing of cases—can result in a rational distribution of services between tertiary care and other hospitals.

We recommend that a birthweight adjustment factor be added to the DRG schema to allow for effective case-mix control, and that the weights be recalibrated by the Health Care Financing Administration or by other financing agencies who use a DRG-based reimbursement system. Such an adjustment must rely on a data base with a sufficiently large number of high-risk cases.

Our findings suggest that the problem of losses identified for the obstetric DRGs is not a case-mix problem; thus, there does not appear to be an adequate rationale for revising the obstetric DRGs. Our findings lead us to conclude that the weights be recalibrated.

PUBLICATIONS

Articles and Chapters

Schwartz RM. 1988. Regionalization in an environment of competition and technological proliferation. *Perinatal Press* 11(1):12–13.

Abstracts

None to date.

Presentations

None to date.



ACCULTURATION, PSYCHOSOCIAL PREDICTORS, AND BREASTFEEDING

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PROJECT NUMBER MCJ-480555

REPORT NUMBER MCH/CCS-91/06

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PROJECT PERIOD 04/01/87-03/31/91

Costs* Year 1 Year 2 Year 3 Year 4 Year 5 Awarded 254,598 320,565 235,084 n/a n/a Requested 254,534 380,585 276,607 n/a n/a

* Indirect included

SUMMARY

Statement of the Problem

The incidence of breastfeeding in the United States has been low compared to the rest of the world and has slowly declined from a peak of 62 percent in 1984 to about 52 percent in 1990. Hispanics and black Americans have breastfed at particularly low rates. In order to ultimately increase the incidence and maintenance of breastfeeding, we investigated the reasons that adaptation to U.S. culture reduces breastfeeding rates in the target population of Brownsville, a city on the border between Texas and Mexico. This population is primarily Hispanic and of low socioeconomic status. A higher breastfeeding rate in this population would engender both health and economic advantages for these mothers and infants.

Research Questions or Hypotheses

This study tested the hypothesis that social, environmental, and cognitive factors are differentially related to initiation of breastfeeding across the spectrum of acculturation from the Mexican culture to the predominant culture of the United States. Specifically, breastfeeding was expected to be highest among the least acculturated Mexican Americans and among Anglo-Americans, and lowest among Mexican Americans in the middle of the acculturation spectrum. The specific aims of the study were to: Characterize the population with respect to acculturation and demographic information; measure the available social support/influence for the population from individuals in the



mother's entironment; measure the behavioral capability and self-efficacy of the mother toward the breastfeeding behavior; determine maternal attitudes toward breastfeeding; measure health and environmental restraints that might impact on the mother's ability to breastfeed; and assess the husband/male partner's involvement in breastfeeding behavior.

Study Design and Methods

Two phases of data collection were conducted, a pilot study of 5 months during which 213 mothers were recruited from a contact population of 331, and a major study of 15 months during which 906 mothers were recruited from a contact population of 1,226. In addition, 119 and 303 male partners were recruited in the pilot and major studies, respectively. Mothers were recruited prenatally, 2–10 weeks before their delivery date, at which time the first interview was conducted. A second interview (natal) was conducted immediately after delivery of the infant, and a third interview (postnatal) was conducted 2–3 weeks after delivery. Male partners were interviewed during the prenatal period. All interviews consisted of a structured series of instruments administered in either English or Spanish (mother's choice) by trained bilingual interviewers. The Spanish version of the instrument was prepared by translation to Spanish and back-translation to English by separate professional translators with experience in the language used in the Brownsville area.

The structured interviews comprised a number of instruments designed to collect data in the areas relevant to the hypothesis being tested. Eight instruments were used: Demographic, Social Support, Infant Feeding, Maternal Attitudes, Maternal/Infant Health. Acculturation, Behavioral Capability, and Self-Efficacy. Demographic and acculturation instruments were administered only at the prenatal interview, with the exception of a few items designed to confirm earlier responses. The behavioral capability instrument was administered at the prenatal and postnatal interviews and the self-efficacy instrument at the prenatal and natal interviews. All other instruments were administered at all three interviews. The male partner questionnaire consisted of instruments on attitudes, feeding, and social support.

Breastfeeding was defined as any breastfeeding at the postnatal interview, indicating that successful initiation of breastfeeding had taken place.

Data were analyzed by collecting frequencies and calculating significance of distributions by chi-square analysis. Associations among variables were calculated by regression analysis and predictor models by logistic regression analysis. Internal consistencies of scales were determined by Cronbach's alpha, and variables within instruments were determined using factor analysis. Scales were developed within each of the instruments to provide indexes to reflect the psychosocial predictors being measured. All variables were analyzed across the acculturation spectrum.

Study Sample and/or Population

The population was recruited from all mothers in Brownsville, Texas, who give birth during the 15-month sampling period. Approximately 3,300 women gave birth during this period; 37.2 percent of these women were contacted and 27.4 percent (N=906) were recruited to participate. The participating mothers reflect the distribution among the



Brownsville population (as reported by the City Health Department) in terms of the four possible birthing sites: Two private hospitals (35 percent and 24 percent, respectively), maternity center (13 percent), and lay midwife *partera* (25 percent). The birthplaces of the subjects' previous children had a similar distribution: Two private hospitals (31 percent and 23 percent, respectively), maternity center (18 percent), and lay midwife (24 percent).

Findings

The population investigated was of Mexican origin and generally of lower socioeconomic status as defined by education and income. These mothers fell primarily within the lower portion of the acculturation scale that we used. Degree of acculturation was closely associated with income, education, age, household size, and occupational prestige score. Approximately 50 percent of the mothers elected to be interviewed in Spanish, the remainder in English.

Approximately 75.3 percent of the mothers indicated at the prenatal interview that they intended to breastfeed. This figure declined to 61.4 percent at the natal interview, and only 44.8 percent had actually initiated breastfeeding successfully at the postnatal interview. Degree of acculturation was strongly associated with the successful initiation of breastfeeding: Of the mothers who successfully initiating breastfeeding, 52.9 percent ranked low on the acculturation scale, 37.6 percent ranked in the middle, and 36.1 percent were highly acculturated.

Four indices of social support were associated with the successful initiation of breastfeeding (Positive Marital Index, Husband/Male Partner Supportive Acts, Consensus on Infant Feeding Index, and the Weighted Influence Score). In general, the more supportive individuals available in the environment, the more likely the mother was to breastfeed, and the husband/male partner was particularly important. Acculturation was negatively associated with the Consensus on Infant Feeding Index, indicating that a change in family support occurs as the mother becomes acculturated. A similar type of association was observed for five variables constructed from different maternal attitudes toward breastfeeding. In particular, maternal attitudes favorable toward breastfeeding had a strong positive association with this behavior, while acculturation was negatively associated with these variables. In contrast, variables constructed indicating negative attitudes toward breastfeeding were negatively associated with this behavior.

Indices measuring self-efficacy and behavioral capability toward breastfeeding indicated that the greater the self-efficacy and behavioral capability expressed by a mother, the more likely she was to breastfeed. Successful initiation of breastfeeding also was associated with previous breastfeeding experience, and place and type of prenatal care. Care in a private physician's office or by an obstetrician was associated with a lower rate of breastfeeding, and reflected the fact that such care was used primarily by more acculturated mothers. Lastly, there was a trend for mothers who participated in the Special Supplemental Food Program for Women, Infants and Children (WIC) to be less



likely to breastfeed and for these mothers to be somewhat less acculturated. However, only a small proportion of the population (20.3 percent) did not participate in WIC.

Recommendations

On the basis of these findings, it would be appropriate to specifically target populations adapting to the wider United States culture for intervention programs designed to increase the rate of breastfeeding. Most of this population appears to have access to WIC, yet the breastfeeding promotion efforts of the program in this area have failed to prevent declines in breastfeeding rates. Thus, further evaluation of the WIC program is warranted. Intervention programs in this population ought to include a number of components reflecting the findings of this project. Programs ought to target both the mother-to-be and the supporting individuals within her environment, particularly her male partner. Prenatal classes ought to strongly emphasize participation of the family, and ought to spend considerable time addressing the benefits of breastfeeding early in the course of pregnancy, to enhance maternal attitudes. These classes also ought to provide information on how to successfully breastfeed and to emphasize the success of other mothers to develop the self-efficacy and behavioral capability of the target population.

Further studies ought to be conducted to delineate the factors involved in successful maintenance of breastfeeding. A project to test an intervention program that emphasizes early intervention during pregnancy would be appropriate. Finally, establishment of breastfeeding support centers directed at both nutrition and behavior ought to be made a part of the WIC program.

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Articles and Chapters

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Rassin DK, Markides KS, Baranowski T, Bee DE, Richardson CJ, Mikrut WD, Winkler BA. In preparation. Acculturation and breastfeeding on the United States-Mexico border.

Rassin DK, Markides KS, Baranowski T, Richardson CJ, Mikrut WD, Bee DE. In preparation. Acculturation and the initiation of breastfeeding.

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Presentations

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Rassin DK. Acculturation and breastfeeding on the United States-Mexico border. Presented before the Society for Pediatric Research, Anaheim, CA. May 1990.

Rassin DK. Acculturation and breastfeeding on the United States-Mexico border. Presented before the Southern Society for Pediatric Research, New Orleans, LA, January 1990.

Rassin DK. Acculturation and breastfeeding: Behavioral capability. Presented before the Southern Society for Pediatric Research, New Orleans, LA, January 1992.

Rassin DK. Acculturation and the initiation of breastfeeding, Presented before the Society for Pediatric Research, New Orleans, LA, May 1991.

Rassin DK. Co-chaired workshop A Model Program in Faculty Research Development and Facilitation, the Society for Pediatric Research, Baltimore, MD, May 1992.

Rassin DK. Impact of maternal attitudes and social support on breastfeeding. Presented before the American Dietetic Association, Dallas, TX. October 1991.



162

178

SICKLE CELL ANEMIA: DNA FOR NEWBORN SCREENING FOLLOWUP

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Costs* Year 3 Year 4 Year 5 Year 1 Year 2 Awarded 73,690 denied denied n/a n/a n/a Requested 88,442 91,280 96,749 n/a

* Indirect included

SUMMARY

Statement of the Problem

This research project addresses the problem of followup to newborn screening for sickle cell anemia using direct DNA confirmatory diagnosis from the initial newborn filter paper blotter. Neonatal hemoglobinopathy screening requires sensitive electrophoretic determination of the abnormal beta-globin. Newborns with a very low proportion of the adult hemoglobin represented by the sickle (S) beta-globin, and with a high proportion of fetal hemoglobin may have an equivocal diagnosis of carrier (AS) versus homozygous affected (SS) status after screening by protein electrophoresis. This confusion can frequently be resolved by confirmatory followup electrophoresis using a liquid blood specimen, although even this may not resolve the issue for a period of 2–4 months, until the adult beta-globin gene is turned on sufficiently.

The major problem that results from equivocal or delayed diagnosis of sickle cell anemia has to do with antibiotic prophylaxis in the patient with SS disease. This therapy may be initiated later than it should be, it may not be started at all, or the family may not continue the antibiotic regimen appropriately. All of these actions place the infant at risk for life-threatening infection, particularly from overwhelming infection due to *Streptococcus pneumoniae*. Infection can occur at 4 months of age and is most likely during the first 3 years of life. The fatality rate in patients with SS disease can be as high as 30 percent with this infection.



Research Questions or Hypotheses

This project evaluates a technical innovation, the extraction of DNA from the dried blood spot from the newborn screening blotter and amplification of the beta-globin gene sequence to allow a rapid and specific followup DNA test for SS disease from the newborn screening blotter.

Study Design and Methods

Specimens are sent from the State newborn screening laboratory at the Texas Department of Health to the DNA followup laboratory at Baylor College of Medicine. These samples are single, half-inch circles cut from neonatal specimen blotters after all routine screening tests have been performed. The identity and electrophoretic results of these are unknown to all of the personnel in the DNA laboratory. The results from the State screening laboratory are revealed only after the DNA genotype has been determined.

A half-inch semicircle is cut from each specimen circle of dried blood using stainless steel scissors which are routinely washed in 0.3N HCl for 10 minutes between samples in order to depurinate DNA and prevent cross-contamination of specimens. Each semicircle represents the dried equivalent of approximately 25 μ l of whole blood. The microextraction procedure is similar to that reported previously, with the exception that the proteinase K digestion is extended from 2 hours to approximately 16 hours (overnight) in order to improve DNA yield. The procedure includes methanol fixation, sodium dodecyl sulfate (SDS) and proteinase K treatment, phenol extraction (3x), chloroform-isopropyl alcohol extraction (2x), ethanol precipitation, and drying the precipitated DNA. After dissolving the DNA in 100 μ l TE (10 mM Tris HCl and 1 mM EDTA, pH 8.0), the quality is evaluated and the concentration is estimated by electrophoresis of a 10 μ l aliquot with standards of known concentration on a 1 percent ME agarose gel which is stained with ethidium bromide. The DNA median yield is 1,500 ng/semicircle (range 900–2,000 ng/semicircle) or approximately 60 ng/ μ l dried equivalent of whole blood (range 36–80 ng/ μ l).

An aliquot of DNA (generally 200–300 ng or 10–20 percent of the microextracted material) is taken for amplification using 2.5 u Thermus aquaticus (Taq) polymerase (Cetus), and reaction buffer and other components as previously describéd, for a reaction volume of 100 µl. A DNA Thermal Cycler (Perkin Elmer Cetus) is used for 30 cycles of amplification: Denaturation 94°C for 0.5 minutes, annealing 55°C for 0.5 minutes and extension 72°C for 1.0 minute. Two primers flanking a 299 base pair (bp) genomic region containing the sickle cell mutation are used: PC0325 and PMC1110 (5'-CTCAAAGAACCTCTGGGTCC-3').

Subsequently, we adapted a method from Schwartz et al. and previous work on boiling of specimens from our group, which avoided the need for manual microextraction. Aliquots measuring approximately 4 mm x 4 mm (representing the dried equivalent of approximately 8 μ l whole blood) are cut from each dried blood specimen and placed in 1.5 ml microcentrifuge tubes to which the complete amplification cocktail including primers (and, in some cases, Taq polymerase) is added as described above. These microfuge tubes are then placed in the automated thermal cycler programmed



164 180 SICKLE CELL ANEMIA

with an initial 15-minute step at 95°C followed by 30 cycles of amplification described above, modified to increase the 94°C denaturation step from 0.5 to 1.0 minute. If Taq polymerase has not been added prior to the initial 15-minute cycle, it is added after this step and before the 30 cycle amplification program is initiated. Following amplification, the tubes are centrifuged, the supernatants removed and aliquoted for analysis.

Four detection methods are used to analyze the amplified products in the blinded assessment of samples from the State screening laboratory. Each method uses $10-20~\mu l$ of the $100~\mu l$ PCR reaction volume. Two of these methods are based on dot-blot or slot-blot hybridizations of amplified DNA with allele-specific oligonucleotide (ASO) probes (p19A and p19S), either labeled with radioactive phosphorus or horseradish peroxidase.

The third approach involves direct digestion of the PCR amplified product with DdeI and separation of the restriction fragments by agarose gel electrophoresis in a method adapted from Kazazian. The fourth method uses Southern blotting and hybridization with radioactive phosphorous-labeled ASOs.

Products of direct amplification reactions are analyzed for the A, S, C, and E alleles using dot-blot or slot-blot hybridizations with radiolabeled ASO probes. The A, S, and C ASOs are 19-mers previously described (p19A, p19S, and p19C), and the E ASO is a 20-mer which we have designated p20E (5'-AAGTTGGTGGTAAGGCCCTG-3').

Microextracted DNA is amplified using oligonucleotide primers flanking the mutation site. Fluorescent DNA sequence primers are prepared and fluorescent DNA sequencing is carried out using the ABI Automated Sequencer.

Study Sample and/or Population

The State Newborn Screening Laboratory sends remains of each newborn screening specimen that had a hemoglobin electrophoresis diagnosis of sickle cell disease carrier or affected. These specimen portions are sent after the State Newborn Screening Laboratory has completed all of the testing. If these specimen remains had not been sent to our laboratory, they would have been discarded.

Findings

The comparison of the hemoglobin electrophoresis results from the State screening laboratory and the initial results from the DNA laboratory revealed complete agreement between the protein-based screens and all 4 DNA analyses in 70 of the 75 specimens. Of the five specimens in which the results disagreed, three were in the group determined to be FA and two in the group determined to be FS by the State laboratory. One specimen from each of these groups required a second specimen circle from the State laboratory for clarification, but the DNA results from the remaining three were clarified using the original circle of dried blood. There was disagreement between the hemoglobin screen and all four DNA analyses from the first microextraction in two of the FA samples; the initial DNA result was AS.

Upon repeat extraction using the remaining semicircle from the original blood spot and reevaluation by all four DNA methods, there was complete agreement between the DNA laboratory (AA) and the State screen (FA), suggesting that the initial disagreement was due to contamination during the first DNA microextraction or the initial PCR



amplification. Interestingly, both of these specimens were microextracted, amplified, and analyzed in the same batch. The DNA laboratory agreed in three out of four analyses (SS) for one of the specimens designated FS by the screening laboratory, and disagreed only with the dot blot (AS). When the remaining half of the original specimen circle was reextracted, reamplified, and reanalyzed, the DNA results agreed completely with the State laboratory, suggesting that the initial disagreement was due to contamination at the dot blot step after aliquoting the amplification products.

The two remaining samples in which results disagreed between the two laboratories required a second specimen circle to be sent to the DNA laboratory from the original blood blotter. The FA sample gave inadequate amplification of the microextracted DNA. Analysis was attempted by ASOs and Southern blotting, and while the results were suboptimal, they were interpreted as FAS. A second circle from the original blotter was requested from the State laboratory and the microextracted DNA again did not support amplification; no analyses were successful from the repeat circle. Both the original and repeat circles of blood from this blotter were unacceptable specimens and in routine practice we would have requested a repeat sample from the patient and would not have reported a genotypic result.

Analysis of the DNA from the final specimen consistently disagreed with the screening laboratory result (FS), the DNA results all showing AS. Four independent microextractions were carried out from two specimen circles sent separately from the original blotter, and the DNA results on all four tests on each extract were consistently AS. We suggested to the State laboratory that these results would be consistent with a disorder such as S/beta-thalassemia, and this was confirmed by additional laboratory testing of the patient. Therefore, this discrepancy was real and resulted in clinically useful information. In actual practice, confirmation would require a new specimen from the patient for clarification.

Following analysis of these 75 specimens, we modified the procedure to use a 16 mm square specimen, representing the dried equivalent of approximately 8 μ l whole blood, for direct amplification without microextraction. The automated amplification program was altered by introduction of an initial 15-minute step at 95°C and increasing the length of the 94°C denaturation step to 1 minute. We have had successful direct amplification in 77 of 78 specimens, which were analyzed for the A, S, C, and E alleles using dot blot hybridization with radiolabeled probe.

Automated direct sequencing after asymmetric PCR was performed successfully on DNA microextracted from newborn screening specimens representing samples with the A, S, and C alleles. Heterozygotes were detected by the presence of two different nucleotides at the same position(s).

Recommendations

In the absence of a DNA genotyping program, all positive and equivocal newborn screening test results would be repeated on a second, liquid blood specimen drawn at 2–4 months of age. The cost of contacting the families and acquiring the followup specimens are significant expenses that are usually not calculated into the overall cost of newborn screening programs. We have demonstrated that DNA genotyping using the



original neonatal screening specimen is feasible and would reduce the number of second specimens required by an estimated 97 percent. In addition, this would provide more detailed genetic information that would permit better informed education and counseling of these families at the initial contact, which we have suggested may improve compliance with antibiotic prophylaxis and medical management.

Based on the results in this study, we have expanded our genotyping capabilities to include not only the A and S alleles, but also the C and E alleles using radiolabeled ASOs. In addition, it would seem possible to expand this diagnostic ability to examine for thalassemias, using an ethnicity-based algorithm. Since we can perform at least 30 analyses on each blood specimen using the microextraction or direct amplification procedures, the addition of the thalassemias to the neonatal DNA genotyping repertoire would be feasible.

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None to date.

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LISTENING PARTNERS: PSYCHOSOCIAL COMPETENCE AND PREVENTION

GRANTEE

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PROJECT PERIOD

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10/01/86-06/01/91

Costs*

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

 192,237
 233,161
 196,089
 100,320
 n/a

 211,085
 229,791
 135,071
 130,165
 n/a

SUMMARY

Statement of the Problem

Many impoverished, isolated, rural mothers raised in socially isolated, hierarchically structured, and relatively nonverbal households have little opportunity to develop a sense of the power of their own minds and voices. With little reliance on their minds or words for problem solving and communication, these women are more likely to turn to power-oriented techniques for influencing their children (much as their own parents did). The developmental position of these women is likely to be associated with authoritarian child rearing strategies and limited appreciation of their children's social and cognitive capacities. Unable to feel the power of their own minds, many of these mothers do not imagine and draw out such capacities in their children. Failing to think and talk things through with their children, the mothers often do not explain what they know nor do they ask their children questions that might help the children generate their own ideas, explanations, and choices. There is documentation in the literature that these parenting practices and attitudes are linked to delays and/or limitations in children's thinking and learning skills, self-concept and self-esteem, and social competence and peer acceptance, and are also linked to increased behavior problems in children. Moreover, the children are left with many of the thinking and parenting strategies of their parents, thus perpetuating these patterns through subsequent generations.

The Listening Partners Program examined the intellectual and social development of white mothers who have children under age 7, and who are impoverished, isolated, and



^{*} Indirect included

living in rural Vermont. The program investigated the relationship of these characteristics to parenting strategies and concepts of these women, and the development of their preschool-age children. Moreover, the program implemented and evaluated a preventive intervention designed to promote women's intellectual and ethical development, which are believed to support development of constructive parenting concepts and strategies and, in turn, development of healthy children.

Research Questions or Hypotheses

The specific research objectives of the study were to:

- 1. Examine the interrelationships among (a) mothers' intellectual reasoning, (b) mothers' ethical reasoning, (c) maternal self-concept, (d) maternal self-esteem, (e) mothers' parental communication strategies and conceptualizations of the child, (f) mothers' social support networks, (g) mother-child interaction, (h) children's perceived competence, and (i) children's interpersonal cognitive problem-solving skills. While there are substantial theoretical bases for linking these components with one another, relevant empirical evidence is limited. Further demonstration and clarification of the interrelatedness of these characteristics can contribute to a fuller understanding of the nature and functioning of each characteristic, improved design and selection of program evaluation and developmental assessment tools, and development of more effective promotive and preventive intervention strategies.
- 2. Gather systematic data on impoverished rural mothers and their interactions with their young children. Limited systematic data are available on the psychological development and parent-child interactions of this population; the vast majority of available research has focused on urban and suburban populations.
- 3. Develop a cost-effective promotive intervention for mothers and young children that is particularly sensitive, both on psychological and practical grounds, to the needs of the rural poor.
- 4. Determine the effects of the Listening Partners intervention on (a) development of the mothers' intellectual and ethical reasoning, (b) maternal self-concept and self-esteem, (c) parental communication strategies and conceptualizations of the child, (d) maternal social support networks, (e) mother-child interaction, and (f) children's perceived competence and interpersonal cognitive problem-solving skills.

Study Design and Methods

Two cohorts of isolated, rural, impoverished mothers of preschool-age children were recruited to the project (N=120, with 59 experimentals and 61 controls). An 8-month weekly intervention was implemented with the experimental group, and each of the available 120 project participants and their children completed interviews and other assessments at three points in time: Preintervention, postintervention (approximately 9 months later), and followup (approximately 9 months following the postintervention) assessments were carried out. Assessments focused on the women's epistemological and



ethical development, their endorsed parent-child communication strategies, actual parent-child interaction, self-esteem, and social support. One study child (closest in age to 4 years, but younger than 7) from each family was observed in mother-child interaction and, if 4–6 years old, this child completed a problem-solving test and a perceived self-competence test.

Study Sample and/or Population

Two cohorts of 60 women (N = 120) were recruited from the same two contiguous and similar rural, impoverished, sparsely populated counties in northeastern Vermont. Given the nature of this rural population, all participants were white. Mothers were eligible to participate in the project if they met the following criteria: (1) Age 17–34 years, (2) at least one child under age 7, (c) living below the Federal poverty level, (d) living in social/rural isolation, (e) family identified by one or more referring agencies as having little family support and at risk for abuse or neglect of the children or under unusual stress, and (f) lack of involvement in support and self-help groups. For purposes of the assessments, the project identified a study child in each family (closest to age 4 but under age 7). This group included 51 girls and 69 boys who ranged in age from 0.2 to 6.8 years at the time of preintervention assessments.

Names of potential project participants were solicited from social service and mental health agencies and professionals in the area. We encouraged referrals of families who had refused participation in other community services. Experimental group was assigned by county of residence, given the likelihood that information about the intervention would spread among members of the community.

Potential participants were told that we were interested in learning more about the lives of rural women and the experience of raising children in rural isolation, and that we wanted to disseminate this story. They were also told that some of the women in the project would have the opportunity to participate in groups designed to help women break through social isolation, gain a voice, feel the power of their minds, and help participants assist their children in talking and thinking through their problems. They were also informed that they would be compensated \$15 at each of three points in time for completing a series of interviews and scales that would require several hours of their time at each sitting.

Findings

Data were coded and analyzed through multiple statistical and descriptive means to address the research questions. Intervention participants who entered the program with less complex epistemologies showed significantly greater epistemological gains than did comparable controls. These gains not only persisted, but, in large part, even increased during the 9-month period following termination of the intervention. Among the intervention participants, epistemological position at project entry significantly predicted epistemological gains over the 18-month study period; those who began the intervention with the least complex epistemologies showed the most gain. Analyses of preintervention assessments supported a variety of hypotheses regarding the relationship between maternal epistemology and other maternal characteristics including parenting. Mothers



with more complex epistemological perspectives had more developed moral maturity and endorsed more cognitively demanding, nonauthoritarian, and nondirective parenting communication strategies—those that are more likely to draw children into active participation and problem solving. Moreover, women with more complex epistemological perspectives used more cognitively engaging statements and questions with their children and focused less upon controlling and/or restraining their children's non-task-related behaviors. Similarly, women who endorsed more nonauthoritarian parent-child communication strategies used more cognitively engaging statements and questions with their children.

Recommendations

Efforts aimed at fostering child development might best focus on facilitating the development of parents and other caregivers. Because only enduring influences have enduring effects, the child's ongoing environment is most able to support transactions that will foster or impede development. At the same time, as we focus upon supporting more effective parenting, it becomes increasingly clear that women's abilities to employ more effective parenting strategies may well depend upon the women's own developmental levels and perspectives. Because mothering strategies do appear linked, in part, to maternal cognitive and social development and understanding, interventions might best focus directly on these characteristics as the foundation for more effective parenting activities as well as happier and healthier adults. In other words, we must consider a parent's developmental readiness to deal with new issues and concepts much as we do children's developmental readiness when we design child-oriented interventions. Moreover, as the Listening Partners model suggests, this approach may foster the development not only of healthier and stronger individuals, but also of peer, parent-child, and community systems that, themselves, serve as self-sustaining promotive interventions. Without such a focus, we may continue to see more child and parent training programs that fail to demonstrate long-lasting effects.

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Abstracts

None to date.

Presentations

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MOTHERING IN ADOLESCENCE: FACTORS RELATED TO INFANT SECURITY

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PROJECT PERIOD 04/01/86–03/31/89

Costs* Year 1 Year 2 Year 3 Year 4 Year 5 Awarded 128,700 151,010 114.049 n a n/a 142,511 Requested 166,047 125,420 n/a n. a

SUMMARY

Statement of the Problem

Adolescent motherhood is becoming more prevalent in all sectors of society, but scientific knowledge of the social and emotional well-being of the children involved lags behind this important demographic change. Specifically, most research on children of adolescent mothers does not include a focus on attachment security. During the past 15 years, research has revealed that attachment is an important predictor of positive child adaptation in the preschool and childhood years. More information is needed on the attachment outcomes of children of adolescent mothers, and on maternal and child factors that affect these outcomes, in order to design appropriate services to help young mothers develop secure attachment relationships with their children. Although the study did not directly address ethnic differences, such issues could be explored in secondary analyses.

Research Questions or Hypotheses

The purpose of this investigation was to determine: (1) The impact of the quality of adolescent mothering on the incidence of insecure attachment; (2) the role of maternal psychosocial variables such as social support, negative affect, and the security or egocentricity of maternal "working models" in determining the quality of infant attachment outcomes; and (3) the effects of demographic and environmental correlates of maternal age (e.g., life stress, low levels of education and income, and extended family living arrangements) on parenting quality and infant attachment outcomes. The



176

^{*} Indirect included

attachment outcomes of interest included attachment classifications, degree of security, and degree of disorganization.

Study Design and Methods

All infants were observed during the Ainsworth Strange Situation Procedure. Mothers and infants were observed and interviewed in the home, and mothers completed a number of questionnaires measuring life events, negative affectivity, self-perceptions, and perceptions of past relations with parents.

Study Sample and/or Population

Subjects included 244 adolescent mothers under 20 years of age and their 1-year-old infants. The sample was recruited from 37 different sources providing education, counseling, or health care to pregnant or parenting adolescents and their children. Of those contacted directly, 65 percent agreed to participate. Seventy-seven percent of the mothers were white; 16 percent were African American; and the remainder were Native American, Hispanic, and Asian. Eighty-six percent of the children were first born: 49 percent were male. The sample was generally healthy; 5 percent of the children weighed less than 2,500 grams at birth.

Findings

The findings confirm that the infants of adolescent mothers show higher rates of insecurity and disorganization than are found in older-mother samples of both high and low social risk. In particular, there are higher rates of avoidance, even for infants classified as secure. More than 25 percent of the infants in the sample were found to belong in the disorganized/disoriented attachment classification, a relatively new classification associated with very problematic childrearing environments.

Insecurity and disorganization were found to be related to structural/demographic variables such as maternal youth, infant male gender, and mother living alone (for male infants) or with partners (for female infants). Mothers who experienced attachment-related trauma in childhood (such as abuse, foster care, death of a parent) or who reported that their own mothers had been unloving and rejecting had more insecure and disorganized infants. This was especially true if a young mother still lived at home with her family; living in the grandmother's home did not result in more optimal rearing environments for these infants, despue the higher socioeconomic status of such family types. Adolescent mothers living with their families showed the poorest quality of parenting behaviors. Adolescent mothers who lived apart from their families and who also reported high levels of support from their grandmothers had the best parenting behaviors and the most secure infants.

Recommendations

This research suggests that adolescents who are rearing infants need a supportive, secure base, and that this secure base is not automatically associated with living in the family home. Interventions in infancy need to focus on the infant-adolescent-grandmother triad, for two reasons: First, the grandmother is the most important source of support for the young mother at this stage, and a good relationship between the two



can facilitate the young mother's development and in turn, her infant's development. Second, the grandmother is the most probable alternative caregiver for the infant, and her positive involvement can guide the infant's development until her granddaughter has achieved the necessary maturity to assume the major caregiving role.

PUBLICATIONS

Articles and Chapters

None to date.

Abstracts

None to date.

Presentations

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EPILEPSY IN PREGNANCY: DEVELOPMENTAL FOLLOWUP OF INFANTS

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PROJECT PERIOD 04/01/87-03/31/90

Costs* Year 4 Year 5 Year 2 Year 3 Year 1 Awarded 103,036 109,300 denied denied denied 103,035 108,177 117,638 125,912 130,749 Requested

* Indirect included

SUMMARY

Statement of the Problem

Despite decades of concern for the children of epileptic mothers who are exposed in utero both to possible adverse effects of antiepileptic drugs and to the biological concomitants of maternal seizures, research efforts to date are incomplete and controversial. There have been descriptions in the medical literature of patterns of malformations attributed to in utero exposure to antiepileptic drugs, but we still cannot predict which pregnancies are most at risk for adverse outcome. In addition, there have not been many studies of the developmental outcome of these children, and the studies that have been done generally lack adequate controls for parental intelligence, anticonvulsant exposure, and maternal seizure frequency.

Research Questions or Hypotheses

The purpose of this study was to: (1) Examine the outcome of infants exposed in utero to antiepileptic drugs and/or to maternal seizures, and compare their outcome to that of a group of infants without such exposure; and (2) look for correlates in pregnancy that may predict adverse outcome.

Study Design and Methods

Both groups of children (exposed and nonexposed) were seen at 8 weeks of age by the study pediatrician for a detailed dysmorphology examination. They were seen again at 12 and 24 months of age for a pediatric examination, health history, and



administration of the Bayley Scales of Infant Development by a psychometrist. Audiology by visually reinforced audiometry was conducted at 12 months. The children's last visit was at 36 months of age, when they again saw the pediatrician for a health history, physical examination, and detailed dysmorphology examination. At this visit, the psychometrist administered the Stanford-Binet Intelligence Scale (Fourth Edition), the motor scale of the Revised Vineland Adaptive Behavior Scales, and a language sample for computing mean length of utterance. The psychometrist also administered the Peabody Picture Vocabulary Test, Form M, to both mother and child.

All examiners (pediatrician, audiologist, and psychometrist) were blind as to whether the children were in the exposed or nonexposed group. However, another physician was available to talk with parents who had specific questions about drug exposure.

Study Sample and/or Population

Pregnant women with epilepsy were recruited for this study from a study of epilepsy in pregnancy conducted by the principal investigator at the Epilepsy Center at the University of Washington. As part of this study, the type and frequency of women's seizures and their drug doses and levels were followed closely. The control group of women without epilepsy or other chronic medical conditions was recruited from the prenatal clinic of the University of Washington Hospital. The case and control groups were matched for age, race, and parity. The control group tended to have more years of education, but the difference was not statistically significant.

We originally planned to recruit 147 women in each group, for a total of 294 children in the study. However, the principal investigator relocated in 1987 and funding was terminated for the study at the Epilepsy Center at the University of Washington. At that time, we stopped recruiting new cases and controls for the followup study, leaving a total of 56 case and 51 control children for the study.

Findings

In the group of women with epilcpsy, 72 percent were treated with one antiepileptic drug during pregnancy. No woman took more than two antiepileptic drugs. Carbamazepine was the drug used most commonly, with phenytoin and phenobarbital second and third.

Immediate pregnancy outcomes were generally good for both the case and control groups. Infants of mothers with epilepsy (case) were more likely to have lower Apgar scores at 5 minutes and to be irritable, and were less likely to be breastfed or to leave the hospital with their mother.

Major malformations were observed either at birth or at the 8-week examination in three cases (choanal atresia, pyloric stenosis, and inguinal hernia) and in two controls (pyloric stenosis and hypospadias). The rate of major malformations may increase as the children are followed over time, since some may not be evident at 8 weeks.

Case children had a statistically significant higher mean number of minor anomalies per child (5.05) than the control children (3.65). No differences were found in the mean number of minor anomalies in children exposed to antiepileptic drug monotherapy as opposed to antiepileptic drug polytherapy, nor did the presence or absence of maternal



180

seizures have an effect. There was no difference in the number of anomalies between children exposed to monotherapy with carbamazepine, phenytoin, or phenobarbital. We did not find a dose response effect of antiepileptic drug on minor anomalies.

Historically, certain dysmorphic features have been associated with fetal exposure to antiepileptic drugs. We found that the children of women with epilepsy were more likely to have a flat nasal bridge, anteverted nares, broad alveolar ridge, hypoplastic toenails, distal digital hypoplasia, wide-spaced eyes and large fontanel, but these trends did not reach statistical significance. The only statistically significant difference was that prominent occiput occurred more commonly in the case group (13.1 percent) than in the controls (0 percent).

Recommendations

The data we have obtained so far support the similarities in features of children exposed to various antiepileptic drugs. Rather than specifically labeling a fetal hydantoin, fetal carbamazepine, or fetal valproate syndrome, we suggest that child ren with dysmorphic features simply be considered to have a fetal anticonvulsant syndrome. In addition to our clinical observations, there is also a theoretical basis for similar antiepileptic drug effects on the fetus. The antiepileptic drugs have similar effects on the adult central nervous system, and have metabolic pathways in common.

Clinicians and patients always seek the safest form of therapy. Given the results of our study, with similar rates of malformations with expo- are to the common antiepileptic drugs, we suggest that maternal antiepileptic drugs be chosen for the most effective maternal seizure control.

Women with epilepsy are deeply concerned not just with their children's appearance but also with their intellectual potential. At the conclusion of this study, we hope to be able to address the neurodevelopmental effects of these medications. This study is continuing with alternate funding, and as we complete the older-age evaluations, we will have data to analyze the development of the children.

PUBLICATIONS

Articles and Chapters

Yerby MS, Leavitt A, Van Allen M, Erickson DM, McCormick KB, Loewenson RB, Sells CJ. Benedetti TJ. In preparation. Congenital anomalies in infants of epileptic mothers.

Yerby MS, Leavitt A, Van Allen M, Sells CJ, McCormick KB, Loewenson RB. 1988. Dysmorphism in infants of mothers with epilepsy. *Epilepsia* 29(5):700.

Abstracts

None to date.

Presentations

None to date.



APPENDIXES



COMPLETED

PROJECTS

PUBLICATIONS

1987-1991



Cumulative List of Publications From Completed Projects, 1987–1991

Abman SH, Accurso FJ, Sokol RJ. 1990. Hypoalbuminemia in young infants with cystic fibrosis. *Journal of Pediatrics* 116:840–841.

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204

217

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	MCR-010429	MCH/CCS-81/04	PB81-219255	A06
PROJECT TITLE	Psychosocial Influence Rural Black Women	es on Patterns of Prenatal Care Among		
INVESTIGATOR	Anna Kline, University Birmingham, AL	of Alabama	-	
	MCJ-015310	MCH/CCS-90/01	PB92-135565	A03
PROJECT TITLE	Pervlopmental Dysfur Children	action in School Age Very Low Birthweig	bt	
INVESTIGATOR	Kathleen G. Nelson, M Birmingham, AL	I.D., University of Alabama		
	MCJ-040523	MCH/CCS-88/10	PB89-223580	A11
PROJECT TITLE	Birth Setting and Mot	ber-Infant Interaction		
INVESTIGATOR	Helen L. Britton, M.D. University of Arizona I Tucson, AZ			
	MCR-060004	MCH/CCS-82/04	PB83-163824	A11
PROJECT TITLE	Child Amputee Prosth	etics Project—Research		
INVESTIGATOR	Yoshi Setoguchi, Univ Los Angeles, CA	rersity of California		
	MCR-060390	MCH/CCS-80/05	PB81-161598	A 07
PROJECT TITLE		veness of Perinatal Medical Care		
INVESTIGATOR	Ronald I. Williams, U Santa Barbara, CA	niversity of California		
	MCR-060420	MCH/CCS-81/09	PB82-141805	A12
PROJECT TELLS	Children's Survival Sk	vills: A Basis for Functioning in Society		
INVESTIGATOR	Jeanne H. Block, Univ Berkeley, CA	versity of California		
	MCR-060435	MCH/CCS-83/02	PB83-162651	A 07



PROB CL TITLU

INVESTIGATOR

Factors Having an Impact on Maternal Role Attainment: The First Year of Motherhood

Romona T. Mercer, University of California San Francisco, CA

Project Number	Report Number	NTIS Order Number	Price Code
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	MCR-060466	MCH/CCS-83/08	PB84-199835	A08
PROJECT TITLE	Model of Adolescent l	Perinatal Risk Bebavior		
INVESTIGATOR	N. Moss, Stanford Un. Stanford, CA	iversity		
	MCJ-060469	MCH/CCS-84/11	PB86-144987	A03
PROJECT TITLE	Birth Experience and	l Parenting in Hispanic Women		
INVESTIGATOR	L. Beckwith, Universi Los Angeles, CA	ity of California		
	MCJ-060472	MCH/CCS-84/03	PB86-150604	A06
PROJECT TITLE	•	ldren's Care Across Health Settings		
INVESTIGATOR	D. B. Dutton, Stanfor Stanford, CA	rd University		
	мсј-060473	MCH/CCS-86/02	PB87-162004	A03
PROJECT TITU	Terminal Device and	d Foot Studies for Child Amputees		
INVESTIGATOR	Y. Setoguchi, Univer Los Angeles, CA	sity of California		
	MCJ-060474	MCH/CCS-86/08	PB87-162947	A15
PROJECT TITLE		and Attitudes: A Multiethnic Study		
INVISHGATOR	M. M. Kaback, Harb Torrance, CA	or-UCLA Medical Center		
	мсј-060475	MCH/CCS-87/20	PB88-173729	A03
PROJECT TITLE		Repeat Cesarean Section or Trial of Labor	•	
INVESTIGATOR	Carol Sheply McClai San Francisco, CA	in, Ph.D., M.P.H., University of California		
	MCJ-060495	MCH/CCS-87/10	PB88-173695	A05
PROJECT TITLE		gnant Adolescents in Prenatal Care		
INVESTIGATOR	Iris F. Litt, M.D., Fe Stanford, CA	rnando Mendoza, M.D., Stanford University	•	
	MCJ-060515	MCH/CCS-90/07	PB92-135540	A04
PROJECT HITT	=	ind Development Program		
ANYSHGATOR	Ruth T. Gross, M.D Stanford, CA	, Stanford University		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-060518	MCH/CCS-89/06	PB89-230759	A05
PROJECT TITLE	Health and Nutritional S	tatus of Mexican-American Children		
INVESTIGATOR	Reynaldo Martorell, Ph.D Stanford University Schoo Ithaca, NY			
	MCJ-060546	MCH/CCS-90/05	PB92-136191	A06
PROJECT TITLE	Pesticide Exposure and P	Pregnancy Outcome		
INVENTIGATOR	Winnie O. Willis, Sc.D., S San Diego, CA	an Diego State University		
	MCJ-060550	MCH/CCS-90/10	PB92-136233	A16
PROJECT TITLE	A Survey of Chronically l	II Children's Use of Time Out of School	1	
INVESTIGATOR	Bonnie Holaday, R.N., D.N University of California San Francisco, CA	S.S., Anne Turner-Henson, R.N., D.S.N.		
	MCJ-060551	MCH/CCS-88/03	PB89-215636	A07
PROJECT TITLE	Infant Mortality Among l County	Indochinese Refugees in San Diego		
INVESTIGATOR	John R. Weeks, Ph.D. ,Ru International Population C San Diego, CA	iben G. Rumbaut, Ph.D. Senter		
	MCJ-060573	MCH/CCS-92/03	PB93-179992	A03
PROJECT TITLE	Laboratory Evaluation of	Jaundiced Newborns: A Recvaluation		
INVESTIGATOR	Thomas B. Newman, M.E. San Francisco, CA	D., M.P.H., University of California		
	MCR-080404	MCH/CCS-83/05	PB84-199983	A05
PROJECT TITLE	Intrapartum Intensive Ca	re and Outcome of the Infant		
INVESTIGATOR	L. O. Lubchenco, Univers Denver, CO	ity of Colorado		
	MCR-080415	MCH/CCS-81/03	PB81-212060	A05
PROJECT TITLE	Combined Developmenta	VEnvironmental Screen		
INVESTIGATOR	William K. Frankenburg, Denver, CO	University of Colorado		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-080508	MCH/CCS-88/05	PB89-218622	A05
PROJECT TITLE	Neonatal Screening at	nd Early Diagnosis of Cystic Fibrosis		
INVESTIGATOR		I.S., Mary C. Reardon, M.D.	·	
	MCJ-090480	MCH/CCS-86/03	PB87-161949	A03
PROJECT TITLE	Neurohehavioral Asses	ssment of Premature Infants		
INVESTIGATOR	E. B. Thoman, Univer Storrs, CT	sity of Connecticut		
	MCJ-090489	MCH/CCS-88/09	PB89-218655	A03
PROJECT TITLE	Can Mothers Identify	the Seriously III Febrile Child?		
INVESTIGATOR	Paul L. McCarthy, M.I New Haven , CT)., Yale University Medical School		
	MCR-110354	MCH/CCS-81/07	PB81-247561	A05
PROJECT TITLE	Nutrition Services in	Perinatal Care		
INVESTIGATOR	Myrtle L. Brown, Nat Washington, DC	ional Research Council		
	MCR-110445	MCH/CCS-83/18a	PB83-158832	A10
РВОЛ-СТ ТІП.	Alternative Dietary I Pregnancy: Proceed	Practices and Nutritional Abuses in ings of a Workshop		
INVESTIGATOR	Myrtle L. Brown, Nat Washington, DC	tional Academy of Sciences		
	MCR-110445	MCH/CCS-83/18b	PB83-152736	A03
PROJECT TITLE	Alternative Dietary l Pregnancy: Summa	Practices and Nutritional Abuse in ry Report		
INVESTIGATOR	Myrtle L. Brown, Na Washington, DC	tional Academy of Sciences		
	MCR-110449	MCH/CCS-83/01	PB83-163790	A09
PROJECT TITLE	Research Issues in t	be Assessment of Birth Settings		
INVESTIGATOR	Enriquetta Bond, Na Institute of Medicine Washington, DC	itional Academy of Sciences		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-110461	MCH/CCS-85/07	PB86-145257	A07
PROJECT TITLE	Maternal Perceptions Development	CNS Organization and Cognitive		
INVESTIGATOR	P. L. Rosse, Howard Washington, DC	University		
	MCJ-110499	MCH/CCS-87/12	PB88-173703	A07
PROJECT TITLE	Mediators of Behavio	ral Problems in Chronic Illness		
INVESTIGATOR	Phyllis R. Magrab. Ph Washington, DC	.D., Georgetown University Medical Center		
	MCJ-110527	MCH/CCS-88/07	PB89-218648	A04
PROJECT ITTLE	Severity of Illness: A	National Study		
INVENTIGATOR	Murray M. Pollack, M Children's Hospital N Washington, DC	.D. ational Medical Center		
	MCJ-110563	MCH/CCS-91/07	PB92-136241	A12
PROJECT TITLE	Interaction and Supp	oort: Mothers and Deaf Infants		
INVESTIGATOR	Kathryn P. Meadow-C Washington, DC	Orlans, Ph.D., Gallaudet Research Institute		
	MCR-120455	MCH/CCS-84/01	PB86-145190	A11
PROJECT TITLE	Drug Information an	d Maternal and Child Health		
INVESTIGATOR	Y. Brackbill, Universi Gainesville, FL	ty of Florida •		
	MCJ-130516	MCH/CCS-92/04	PB93-179984	A04
PROJECT TETLE	ldentification of Risk	for SIDS: Subsequent Siblings		
INVESTIGATOR	Alfred Steinschneider Atlanta, GA	, M.D., Ph.D., American SIDS Institute		
	MCJ-130549	MCH/CCS-88/04	PB89-218614	A03
PROJECT TILLF	Race and Risk for SH	DS		
ANVESTIGATOR	Philip S. Spiers, Ph.D Atlanta, GA	The American SIDS Institute		
	MCR-170456	MCH/CCS-83/16	PB84-200682	A03
PROJECT TITLE	Manpower and Facil Health—II	ity Planning for Maternal and Child		
INVESTIGATOR	W. Pearse, American Washington, DC	College of Obstetricians and Gynecologists		



	MCJ-170500	MCH/CCS-87/13	PB88-100045	A14
PROJECT TITAL	Medical Genetics: A l	egal Frontier		
INVESTIGATOR	Lori B. Andrews, J.D., Chicago, H.	American Bar Foundation		
	MCJ-180492	MCH/CCS-85/06	PB86-152329	A03
PROJECT TITLL)evelopmental Disabilities		
INVESTIGATOR	R. C. Perez, Indiana U Indianapolis, IN	'niversity 1' (rdue University		
	MCR-190260	MCH/CCS-81/01	PB81-186959	A02
PROJECT THEF	Infant Feeding and C Serum Cholesterol at	Growth as Related to Indices of Fatnes. Age 8 Years	s and	
INVISHGAIOR	Samuel J. Fomon, Io Iowa City, IA	wa University		
	MCR-190356	MCH/CCS-80/03	PB81-176448	A08
PROJECT TITA	Restoration of Funct	ion to Congenitally Deformed Hands.	Part 1	
INVESTIGATOR	Adrian E. Flatt, Iowa Iowa City, IA	University		
	MCR-190419	MCH/CCS-82/08	PB83-163568	A03
PROJECT HITE	Urinary Urea Nitrog	en as an Indicator of Pregnancy Risk		
INVESTIGATOR	Frank J. Zlatnick, Io Iowa Caty, IA	wa University		
	мсј-190457	MCH/CCS-86/04	PB87-161956	A06
ркоп ст тит	Psychosocial Aspect	s of Genetic Counseling		
INVESHIGATOR	E. E. Ekwo, Univers Iowa City, IA	ity of Iowa		
	MCJ-190490	MCH/CCS-84/10	PB86-145224	A04
PROJECT 11111	Evaluation of Meas	ures Assessing Genetic Counseling		
INVESTIGATOR	M. L. Wolraich, Uni Iowa City, IA	versity of lowa		
	MCJ-190572	MCH/CCS-92/01	PB93-180206	A04
ркор ст 11111	Nature Origins, ar	ad Consequences of Conceptions of Pa	renting	
INVESTIGATOR	Ronald L. Simons, S Ames, IA	Ph.D., Iowa State University		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCR-200442	MCH/CCS-81/10	PB82-140732	A04
PROJECT TITLE	Training UAF Studer	us in a Behavioral Preschool	1202 110/92	ACT
INVESTIGATOR		ity of Kansas Medical Center		
	MCJ-210577	MCH/CCS-92/10	PB93-181857	A03
PROJECT TITLE	"High Tech" Home C Conditions	Care for Children with Chronic Health		
INVESTIGATOR	Juanita W. Fleming, P University of Kentuck Lexington, KY	h.D., Barbara Teague, R.N., M.S.N., C.P.N.A. y		
	MCJ-220556	MCH/CCS-91/03	PB92-136225	A07
PROJECT TITLE	Intravenous Autibiot Hospital	ic Therapy in Cystic Fibrosis: Home Versus		,
INVESTIGATOR	William W. Waring, New Orleans, LA	A.D., Tulane University School of Medicine		
	MCJ-230506	MCH/CCS-87/03	PB87-199030	A06
PROJECT TITLE	Impact of Variations Prenatal Care Utiliza	in AFDC and Medicaid Eligibility on ttion		
INVESTIGATOR	Andrew F. Coburn, P University of Southern Portland, ME	h.D. Thomas P. McDonald, Ph.D. n Maine		
	MCJ-240291	MCH/CCS-87/05	PB87-199055	A04
PROJECT TITLE	Validation of an Ear	ly Screen for Cerebral Palsy		
INVESTIGATOR	Frederick B. Palmer, Baltimore, MD	M.D., John F. Kennedy Institute		
	MCR-240392	MCH/CCS-81/13	PB83-165357	A21
PROJECT TITLE	Primitive Reflex Profi Volumes I and II	le: Early Motor Diagnosis,		
INVESTIGATOR	Arnold J. Capute, Joh Baltimore, MD	n F. Kennedy Institute		
	MCR-240405	MCH/CCS-80/02	PB81-162901	A11
PROJECT TITLE	Feasibility and Effect Screening	iveness of Obtaining Consent for Neonatal		
INVESTIGATOR	Ruth Faden, Johns Ho Baltimore, MD	opkins University		



	MCR-240418	MCH/CCS-81/02	PB81-188526	A05
PROJECT TITLE	Interdisciplinary Rese	arch on Physical Rehabilitation		
INVESTIGATOR	Michael F. Cataldo, Jo Baltimore, MD	shn F. Kennedy Institute		
	MCR-240421	MCH/CCS-84/04	PB86-150596	A11
PROJECT TITLE	Assessment of the Imp	pact of the IPO Project		
INVESTIGATOR	Donna M. Strobino, J. Baltimore, MD	ohns Hopkins University		
	MCR-240422	MCH/CCS-82/06	PB83-163550	A08
PROJECT TITLE	Research Study to Im	prove Teenage Contraception Practices		
INVESTIGATOR	Theodore M. King, Jo Baltimore, MD	ohns Hopkins University		
	MCR-240426	MCH/CCS-82/10	PB83-163857	A10
PROJECT TITLE	•	pacts of Children's Handicaps		
INVESTIGATOR	David S. Salkever, Jo Baltimore, MD	hns Hopkins University		
	MCR-240436	MCH/CCS-83/19	PB84-200708	A07
PROJECT TITLE	Evaluation Study	and Counseling in Alpha-Fetoprotein: A	n	
INVESTIGATOR	Ruth Faden, Johns H Baltimore, MD	lopkins University		
	MCR-240441	MCH/CCS-81/05	PB81-249195	A09
PROJECT TITLE	Standardization of	the Miller Assessment for Preschoolers		
INVESTIGATOR	Lucy Miller, America Rockville, MD	nn Occupational Therapy Association		
	MCR-240447	MCH/CCS-83/03	PB83-163634	A07
PROJECT TITLE		espeech Skills in Young Children		
INVESTIGATOR	Rachel E. Stark, Joh Baltimore, MD	n F. Kennedy Institute		
	MCR-240451	MCH/CCS-83/07	PB84-199827	A07
PROJECT TITLE	Effects of Maternal	Employment on the Use of Pediatric Servi	ces	
INVESTIGATOR	C. S. Alexander, Jol Baltimore, MD	hns Hopkins University		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-240458	MCH/CCS-89/13	PB90-149832	A05
PROJECT TITLE	Trace Metal Interaction	ns in Lead-Exposed Children		
INVESTIGATOR	J. Julian Chisolm, M.I John F. Kennedy Instit Baltimore, MD	D., David J. Thomas, Ph.D. tute		
	MCJ-240463	MCH/CCS-87/15	PB88-173828	A12
PROJECT TITLE	Neurodevelopmental i	Precursors of Learning Disability		
INVESTIGATOR	Arnold J. Capute, M.F John F. Kennedy Instit Baltimore, MD	D., M.P.H., tute for Handicapped Children		
	MCJ-240493	MCH/CCS-88/01	PB88-239660	A05
PROJECT TITLE	Determinants of Infa	nt Feeding: Breast Versus Bottle		
INVESTIGATOR		Johns Hopkins University		
	MCJ-240498	MCH/CCS-87/19	PB88-173752	A15
PROJECT ITTLE	Factors Associated wi Aged 1-9 Years	th Accidental Injuries in Urban Children		
INVESTIGATOR	Donna M. Strobino, P Baltimore, MD	h.D., Johns Hopkins University		
	MCJ-240504	MCH/CCS-87/02	PB87-199022	A04
PROJECT TITLE		ctors Among Handicapped Children		
INVESTIGATOR	Dr.P.H.	7., Dr.P.H., Mary I. Benedict, M.S.W.,		
	The Johns Hopkins U Baltimore, MD	niversity School of Public Health		
	MCJ-240510	MCH/CCS-90/08	PB92-139054	A02
PROJECT TITLE	Course of Recovery fo	r Closed Head Trauma in Adolescence		
INVESTIGATOR	Felix P. Heald, M.D., Baltimore, MD	University of Maryland at Baltimore		
	MCJ-240532	MCH/CCS-90/06	PB92-139021	A03
PROJECT TETLE	Child Care Arrangem	ients and Acute Illnesses in Preschoolers		
INVESTIGATOR	Cheryl S. Alexander, Saltimore, MD	Ph.D., Johns Hopkins University		,



	Project Number	Report Number	NTIS Order Number 1	Price Code
	MCJ-240545	MCH/CCS-89/12	PB90-147422	A 06
PROJECT TITLE	=	Maternity Care for the Poor and	,	
·	Uninsured			
INVESTIGATOR	Richard G. Frank, Ph. Baltimore, MD	D., Johns Hopkins University		
	MCR-250437	MCH/CCS-83/14	PB84-199751	A 06
PROJECT TITLE	Community Child He	alth Studies		
INVESTIGATOR	D. Klien-Walker, Harv Cambridge, MA	eard University School of Public Health		
	MOD 250460	MCH/CCS-84/07	PB86-151040	A04
	MCR-250460		1 B00-1) 10 X	
PROJECT TITLE INVESTIGATOR	-	cup of Preterm and Term Infants i's Hospital Medical Center		
INVESTIGATOR	Boston, MA	та получии послей осто		
	MCR-250462	MCH/CCS-83/15	PB84-200641	A04
PROJECT TITLL	Longitudinal Studies	of At-Risk Adolescents and Families		
INVESTIGATOR	S. T. Hauser, Massacl Boston, MA	husetts Mental Health Center		
	MCJ-250484	MCH/CCS-87/17	PB88-173679	A02
PROJECT TITLE	Risks of Medication .	Procedures in Hospitalized Children		
INVESTIGATOR	Allen A. Mitchell, M. Brookline, MA	D., Children's Hospital		
	MCJ-250501	MCH/CCS-87/11	PB88-173711	A03
PROJECT TITLE	•	KU and Hyperphenylalaninemia		
INVESTIGATOR		o., Susan E. Waisbren, Ph.D.		
	MCJ-250533	MCH/CCS-90/03	PB92-136217	A13
PROJECT TITLE	<u>-</u>	ion Collaborative Study: Phase One		
INVESTIGATOR	Tack P. Shonkoff, M			
	MCJ-250537	MCH/CCS-92/02	PB93-180008	A03
PROJECT TITLE	Stress, Bleeding, an	d Functional Status in Hemophilia		
INVESTIGATOR		D., Massachusetts General Hospital		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-250559	MCH/CCS-90/09	PB92-139047	A03
PROJECT TITLE	Infants of Depressed	Adolescent Mothers		1105
INVESTIGATOR		r, M.D., Boston City Hospital		
	MCJ-250590	MCH/CCS-91/10	PB92-161132	A03
PROJECT TITLE	State Census of Tech	nology-Dependent Children		
INVESTIGATOR	Judith S. Palfrey, M.I Boston, MA	D., Children's Hospital		
	MCJ-253138	MCH/CCS-85/05	PB88-219647	A11
PROJECT TITLE	Need Indicators in A	laternal and Child Health Planning		
INVESTIGATOR	Lorraine V. Klerman, New Haven, CT	Dr.P.H., Yale University School of Medicin	e	
	MCJ-260470	MCH/CCS-89/01	PB89-230775	A05
PROJECT TITLE	SIDS Loss: Psychosoc	ial Impact and Predictors of Coping		
INVESTIGATOR	Camille B. Wortman, University of Michiga Stony Brook, NY	Ph.D., Roxane L. Silver, Ph.D. n		
	MCR-260519	MCH/CCS-89/04	PB89-230791	A09
PROJECT THEE	Consequences for Ch	ildren of Paternal Unemployment		
INVESTIGATOR	Lewis H. Margolis, M Chapel Hill, NC	.D., M.P.H., University of Michigan		
	MCJ-260543	MCH/CCS-91/08	PB92-136209	A07
PROJECT TITLE	Grandfather Influen	ce on Young Children of Teenage Mothers		
INVESTIGATOR	Norma E. Radin, Ph.I Ann Arbor, MI	D., University of Michigan		
	MCJ-260554	MCH/CCS-91/04	PB92-135573	A05
PROJECT TITLE	Improving Memory o	f EMR Children		
INVESTIGATOR	Hilary H. Ratner, Ph. Detroit, MI	D., Wayne State University		
	MCJ-260560	MCH/CCS-91/02	PB92-135532	A02
PROJECT ITTIE	Anthropomorphic Sta Nutritional Status	indards for the Evaluation of Growth and		
1NV1 STIGATOR	Roberto A. Frisancho Ann Arbor, MI	, Ph.D., University of Michigan		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCR-270416	MCH/CCS-83/21	PB84-199942	A07
PROJECT TETLE	Early Maladaptation	: A Prospective-Transactional Study		
INVESTIGATOR	B. Egeland, Universit Minneapolis, MN	ty of Minnesota		
	MCR-270439	MCH/CCS-83/06	PB84-200658	A15
PROJECT TILL		nse Turnover in NICU's		
INVESTIGATOR	M. L. Duxbury, Univ Minneapolis, MN	ersity of Minnesota		
	MCR-280438	MCH/CCS-82/01	PB83-162693	A 06
PROJECT ITTLE	**	iong AFDC Children		
INVESTIGATOR	Mickey C. Smith, Ur University, MS	niversity of Mississippi		
	MCJ-340448	MCH/CCS-85/01	PB86-150612	A10
PROJECT TITLE	Study of Alternative	Birthing Sites		
INVESTIGATOR	L. Z. Ziskin, New Je Trenton, NJ	rsey State Department of Health		
	MCJ-360402	MCH/CCS-84/08	PB88-227392	A13
PROJECT TITE		me Care Unit as an Ambulatory ICU		
INVESTIGATOR	R. E. K. Stein, Alber Bronx, NY	rt Einstein College of Medicine		
	MCR-360403	MCH/CCS-83/20	PB84-199777	A08
PROJECT TITLE	Prenatal Early Info	mcy Project		
INVESTIGATOR	D. L. Olds Comprehensive Int Elmira, NY	erdisciplinary Developmental Services, Inc.		
	MCR-360409	MCH/CCS-80/04	PB81-161606	A13
PROJECT HILE	Bebarioral Develop	oment of Multihandicapped Children		
RNESHGAFOR	Stella Chess, New New York, NY	York University Medical Center		
	MCJ-360440	MCH/CCS-86/01	PB88-233788	A05
PROFICE TITE	Regional Prenatal Acceptance	Diagnostic Services: Needs, Provision and		
INVESTIGATOR	Klaus J. Roghman Rochester, NY	n, Ph.D., University of Rochester		





232

	MCJ-360507	MCH/CCS-87/16	PB88-173661	A03	
РКОЛСТ ППП	Retrospective Study of	Hemoglobin Variants in Newborns			
INVESTIGATOR	Kenneth A. Pass, Ph.I Albany, NY) , New York State Department of Health			
	MCJ-360509	MCH/CCS-88/12	PB89-218598	A03	
PROHET THEF		antidote for Childbood Lead Poisoning			
INVESTIGATOR	Joseph H. Graziano, l New York, NY	Ph.D., Columbia University			
	MCJ-360511	MCH/CCS-89/08	PB90-147984	A08	
PROJECT HITE	Cost of Followup Car	e for Prematures			
INVESTIGATOR	Klaus J. Roghmann, Ph.D. University of Rochester Medical Center Rochester, NY				
	MCJ-360514	MCH/CCS-87/09	PB88-173281	A03	
ркон ст 1111	Prevalence of von W				
INVESTIGATOR	Connie, H. Miller, M.D., New York State Department of Health Albany, NY				
	MCJ-360522	MCH/CCS-88/06	PB89-218630	A03	
PROILCE ATTI	•	atal Chlamydial Eye Infection			
INVESTIGATOR	Margaret R. Hammerschlag, M.D., State University of New York Brooklyn, NY				
	MCJ-360524	MCH/CCS-87/01	PB87-199014	A03	
рконст ПП	Assessment of Diagn	nostic Tests for Chlamydia			
INVESTIGATOR	Sally S. Hipp, Ph.D., New York State Dep Albany, NY	Yangsook Han, M A artment of Health			
	MCJ-360528	MCH/CCS-88/11	PB89-220917	A08	
PRODEL 11111		ly of Service Usage by a Rubella Cobort			
INVESTIGATOR	Patricia R. Cohen, P Hygiene, Inc. New York, NY	h D., Research Foundation for Mental			
	MCJ-360534	MCH/CCS-89/07	PB90-147992	A05	
PROJECT TUILI	Neonatal Outcome	and Weight Gam of Black Adolescents			
INVESTIGATOR	Elizabeth R. McAna Rochester, NY	rney, M.D., University of Rochester			



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-360542	MCH/CCS-89/05	PB89-230817	A03
PROJECT TITLE	Pilot Screening for B	iotinidase Deficiency in Newborns		
INVESTIGATOR	Kenneth A. Pass, Ph. Albany, NY	D., New York State Department of Health		
	MCR-370424	MCH/CCS-82/02	PB83-162743	A12
PROJECT TITLE	Controlled Evaluation Carolina	n of Regional Perinatal Care in North		
INVESTIGATOR	Earl Siegel, University Chapel Hill, NC	y of North Carolina		
	MCR-370427	MCH/CCS-82/09	PB83-163642	A09
PROJECT TITLE	Simultaneous Screen Development and Co	ing of Child Health and Development: Test neurrent Validity	,	
INVISTIGATOR	Raymond A. Sturner, Durham, NC	Duke University		
	MCJ-370427	MCH/CCS-85/04	PB86-150240	A07
PROJECT TITLE		ing of Child Health and or Test Development, Field Testing, and		
INVESTIGATOR	Raymond A. Sturner, Durham, NC	Duke University		
	MCJ-370521	MCH/CCS-89/02	PB89-230767	A04
PROJECT TITLE	Stress, Social Support Infants	, and Abuse and Neglect in High-Risk		
INVESTIGATOR	Jonathan B. Kotch, M University of North C Chapel Hill, NC			
	MCJ-370588	MCH/CCS-92/06	PB93-179976	A05
PROJECT TITLE	Risk Detection Using	Observations of Interaction		
INVESTIGATOR	Julie A. Hofheimer, I Chapel Hill, NC	Ph.D., University of North Carolina		
	MCJ-370603	MCH/CCS-92/05	PB93-180347	A03
PROJECT TITLE INVESTIGATOR		the Risk of Diarrhea in Child Care Centers I.D., M.P.H., University of North Carolina	•	



Project_Number	Report Number	NTIS Order Number	Price Code

	MCR-390337	MCH/CCS-80/01	PB81-161614	A03
PROJECT TITLE	Mother to Infant Attac	chment		
INVESTIGATOR	John H. Kennel, Case Cleveland, OH	Western Reserve University		
	MCR-390400	MCH/CCS-81/11	PB83-163899	A23
PROJECT FITEF	University Affiliated I Status of Developmen	facilities Collaborative Study of Nutrition Itally Delayed Children	al	
INVESTIGATOR	Taylor Whittle, Ohio : Columbus, OH	State University		
	MCR-390430	MCH/CCS-84/02	PB86-145208	A04
PROJECT TITLE	Parent-Infant Attach Full-Terms	ment: New Approaches to Prematures ar	ıd	
INVESTIGATOR	John H. Kennel, Rain Cleveland, OH	bow Babies' and Children's Hospital		
	MCR-390450	MCH/CCS-84/05	PB86-151149	A05
PROJECT TITLE	Validation of an Inte	erdisciplinary Screening Tool		
INVESTIGATOR	W. E. Loadman, Ohio Columbus, OH	o State University		
	MCR-390452	MCH/CCS-81/14	PB83-165217	A08
PROJECT TITLE		rentials in Infant Mortality		
INVESTIGATOR	Edward G. Stockwel Bowling Green, OH	I. Ph.D Bowling Green State University		
	MCR-390453	MCH/CCS-82/05	рв83-162701	A04
PROJECT TITLE	Demographic Influe	nce of Annual Down Syndrome Births		
INVESTIGATOR	Carl A. Huether, Un Cincinnati, OH	iversity of Cincinnati		
	MCJ-390494	MCH/CCS-87/14	PB88-173810	A03
PROJECT TITT	Epidemiological Asf	pects of Down Syndrome		
INVESTIGATOR	Carl A. Huether, Ph Cincinnati, OH	.D., University of Cincinnati		
	MCJ-390520	MCH/CCS-86/09	PB87-160396	A07
PROFEG 11111	Socioeconomic Cor	relates of Infant Mortality		
INVESTIGATOR	Edward G. Stockwo Bowling Green, Of	ell, Bowling Green State University I		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCJ-390548	MCH/CCS-89/09	PB90-147471	A11
PROJECT TITLE	Improving Auditory	Testing of Multibandicapped Children		
INVESTIGATOR	Donald P. Gans, Ph.I Kent State University Kent, OH	D., Karen Derk Gans, Ph.D		
	MCJ-390557	MCH/CCS-91/01	PB92-135557	A03
PROJECT TITLE	Prediction of Outcon	ie of Early Intervention in Failure to Thrii	ષ્ટ	
INVESTIGATOR	Dennis D. Drotar, Ph Cleveland, OH	.D., Case Western Reserve University		
	MCR-420385	MCH/CCS-81/12	PB83-162735	A04
PROJECT TITLE		or Congenital Hypothyroidism		
INVESTIGATOR	Thomas P. Foley, Un Pittsburgh, PA	iversity of Pittsburgh		
	MCR-420399	MCH/CCS-83/10	PB84-199801	A06
PROJECT TITLE	Blood Pressure in Inj Women	fants of Hypertensive and Normotensive		
INVESTIGATOR	J. S. Mausner, Medica Philadelphia, PA	d College of Pennsylvania		
	MCR-420406	MCH/CCS-82/03	PB83-164657	A08
PROTECT TITLE	Child Abuse: An Eva	duation of a Residential Program		
INVESTIGATOR	Elizabeth Elmer, Pare Pittsburgh, PA	ental Stress Center		
	MCJ-420434	MCH/CCS-84/09	PB86-145216	A03
PROJECT TITEF	Myringotomy/Tympa	nostomy Tubes for Otitis Media		
INVESTIGATOR	C. D. Bluestone, Chil Pittsburgh, PA	dren's Hospital of Pittsburgh		
	MCR-420467	MCH/CCS-83/22	PB84-200690	A03
PROJECT TITLE	Facilitating Parental	Involvement: The Newborn Period		
INVESTIGATOR	J. Belsky, Pennsylvar University Park, PA	nia State University		
	MCJ-420496	MCH/CCS-88/02	PB88-239678	A04
PROJECT TEEL	Controlled Study of I	Prematurity Prevention: Efficacy and Cost	s	
INVESTIGATOR	Denise M. Main, M.F. San Francisco, CA	D., University of California		



	Project Number	Report Number	NTIS Order Number	Price Code
		**************************************	nneo 220 4 02	A03
	MCJ-420512	MCH/CCS-89/03	PB89-230783	AUJ
PROPERT TITLE INVESTIGATOR		chian Tube Function and Otitis Media M.D., Children's Hospital of Pittsburgh		
	MCJ-420547	MCH/CCS-89/10	PB90-147430	A03
PROJECT TITLE	Cobort Study of Uterir	ne Contractions in Black Women		
INVESTIGATOR	Denise Main, M.D., U San Francisco, CA	niversity of Pennsylvania		
	MCJ-430503	MCH/CCS-85/08	РВ86-145265	A07
PROJECT TITLE	Epidemiology of Child Motor Vehicle in Pue	l Pedestrian Injury by Collision with a rto Rico		
INVESTIGATOR	A. Navarro, University San Juan, PR	r of Puerto Rico		
	MCJ-440502	MCH/CCS-87/04	PB87-199048	A07
PROJECT TITLE	• •	Childhood Chronic Illness		
INVESTIGATOR	Thomas F. Anders, M The Emma Pendleton East Providence, RI	.D., Judith R. Williams, Ph.D. Bradley Hospital		
	MCJ-440525	MCH/CCS-89/11	PB90-147448	A05
PROJECT TITLE	Diagnosis Related Gi Perinatal Regionaliz	roups (DRGs) and Their Impact on ation		
INVESTIGATOR	Rachel M. Schwartz, Women and Infants' Providence, RI	M.P.H. Hospital of Rhode Island		
	MCR-470428	MCH/CCS-83/13	PB84-199843	A05
PROJECT ITTLE	Linguistic Skills of C	bildren with Monaural Deafness		
INVESTIGATOR	F. H. Bess, Vanderb Nashville, TN	lt University		
	MCJ-470471	MCH/CCS-86/06	PB87-160461	A04
PROJECT THEE	Black Teenage Fath	ers and Their Nonfather Peers		
INVESTIGATOR	F. P. Rivara University of Tennes Memphis, TN	see Center for the Health Sciences		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCR-480464	MCH/CCS-83/04	PB84-199819	A12
PROJECT TITLE	Quality of Maternity			
INVESTIGATOR	Houston, TX	rsity of Texas Health Science Center		
	MCJ-480485	MCH/CCS-85/03	PB86-145240	A09
PROJECT TITLE	Quality of Maternity	Care in Rural Texas		
INVESTIGATOR	G. E. Sussman Southwest Center for Houston, TX	the Study of Hospital and Health Care Systo	ems	
	MCJ-480555	MCH/CCS-91/06	PB92-136126	A04
PROJECT TITLE	Acculturation, Psych	osocial Predictors, and Breastfeeding		
INVESTIGATOR	David K. Rassin, Ph.I Galveston, TX	D., University of Texas Medical Branch		
	MCJ-480561	MCH/CCS-92/11	PB93-180016	A04
PROJECT TITLE	Uterine Activity Patte	rns: Definition with Home Monitor		
INVESTIGATOR	Robert K. Creasy, M. Houston, TX	D., University of Texas Medical School		
	MCJ-480566	MCH/CCS-91/05	PB92-135813	A03
PROJECT TITLE		DNA for Newborn Screening Followup		
INVESTIGATOR	Edward R. B. McCab Houston, TX	e, M.D., Ph.D., Baylor College of Medicine		
	MCJ-500541	MCH/CCS-91/09	PB92-136076	A06
PROJECT TITLE	Listening Partners: I	Sychosocial Competence and Prevention		
INVESTIGATOR	Lynne A. Bond, Ph.E University of Vermon Burlington, VT)., Mary Field Belenky, Ed.D. t		
	MCR-510454	MCH/CCS-83/12	PB84-199975	A03
PROJECT TYTLE		bird Grade Children for Seizures		
INVESTIGATOR	F. E. Dreifuss, Univer Charlottesville, VA	rsity of Virginia		
	MCJ-530048	MCH/CCS-86/07	PB87-160370	A03
PROJECT TITLE		nophen Use by Pregnant Women and Attention Decrements, Height, Weight, wnce		
INVESTIGATOR	•	Iniversity of Washington		



	Project Number	Report Number	NTIS Order Number	Price Code
	MCR-530348	MCH/CCS-81/08	PB82-140740	A12
PROJECT TITLE	Premature Infant Ref	ocus		
INVESTIGATOR	Kathryn E. Barnard, U Seattle, WA	Iniversity of Washington		
	MCR-530351	MCH/CCS-82/07	PB83-162669	A08
PROJECT TITLE	Measures to Predict C	Child Abuse: A Validation Study		
INVESTIGATOR	Mildren Å. Disbrow, Seattle, WA	Universit of Washington		
	MCR-530411	MCH/CCS-81/06	PB81-247579	A08
PROJECT TITLE	Prenatal Correlates of	• ••		
INVESTIGA FOR	Sharon Landesman-D Seattle, WA	wyer, University of Washington		
	MCR-530414	MCH/CCS-83/17	PB84-200716	A02
PROJECT TILLE	Intervention with Hig	gh Frequency Crying (Colic)		
INVESTIGATOR	T. S. Hyde, Universit Seattle, WA	y of Washington		
	MCR-530431	MCH/CCS-83/11	PB84-200724	A03
PROJECT TITLE	Prematurity, Mother	-Infant Interaction, and Language		
INVESTIGATOR	Keith A. Crnic, Universe Seattle, WA	ersity of Washington		
	MCJ-530513	MCH/CCS-87/08	PB88-174420	A10
PROJECT TITLE	Adaptation in Fami	lies of Children with Special Needs		
INVESTIGATOR	Steven P. Schinke, F New York, NY	Ph.D., University of Washington		
	MCJ-530535	MCH/CCS-90/02	PB92-139039	A04
PROJECT TITLE	Mothering in Adole	scence: Factors Related to Infant Security		
INVESTIGATOR	Susan J. Spieker, Ph Seattle, WA	a.D., University of Washington		
	MCJ-530538	MCH/CCS-87/18	PB88-173687	A03
PROJECT TITLE	Prenatal Aspirin ar	id Acetaminophen: 7-Year Follow-Up		
INVESTIGATOR	Ann P. Streissguth, University of Washi Seattle, WA	Ph.D., Helen M. Barr, M.S. ngton		



Project Number Report Number NTIS Order Number Price Code

MCJ-530552 MCH/CCS-90/04 PB92-135870 A03

PROJECT TITLE Epilepsy in Pregnancy: Developmental Followup of Infants

INVESTIGATOR Mark S. Yerby, M.D., M.P.H., University of Washington Seattle, WA



INDEXES



Grantee Index

Baylor College of Medicine	163
Boston City Hospital	82
Case Western Reserve University	142
Children's Hospital	86
Children's Hospital of Pittsburgh	147
Gallaudet Research Institute	35
John F. Kennedy Institute	49
Johns Hopkins University	60, 63
Kent State University	135
New York State Department of Health	126
San Diego State University	22
Stanford University	6
Stanford University School of Medicine	14
Tulane University School of Medicine	44
University of Alabama at Birmingham	3
University of California at San Francisco	28
University of Maryland at Baltimore	56
University of Massachusetts Medical School	67
University of Michigan	1, 99, 103, 115
University of North Carolina at Chapel Hill	129
University of Pennsylvania	150
University of Rochester	122
University of Rochester Medical Center	118
University of Texas Medical Branch at Galveston	158
University of Vermont	170
University of Washington	176, 179
Wayne State University	109
Women and Infants' Hospital of Rhode Island	153



253 243

Project Index

A Survey of Chronically Ill Children's Use of Time Out of School	28
Acculturation Psychosocial Predictors, and Breastfeeding	158
Adenoidectomy, Eustachian Tube Function and Otitis Media	147
Child Care Arrangements and Acute Illnesses in Preschoolers	60
Cohort Study of Uterine Contractions in Black Women	150
Consequences for Children of Paternal Unemployment	99
Cost of Followup Care for Prematures	118
Course of Recovery for Closed Head Trauma in Adolescence	56
Developmental Dysfunction in School Age Very Low Birthweight Children	3
Diagnosis Related Groups (DRG) and Their Impact on Perinatal Regionalization	153
The Farly Intervention Collaborative Study	67
Enilepsy in Pregnancy: Developmental Followup of Infants	179
Grandfather Influence on Young Children of Teenage Mothers	103
Health and Nutritional Status of Mexican-American Children	14
Impacts of Financing Maternity Care for the Poor and Uninsured	63
Improving Auditory Testing of Multihandicapped Children	135
Improving Memory of EMR Children	109
The Infant Health and Development Program	6
Infants of Depressed Adolescent Mothers	82
Interaction and Support: Mothers and Deaf Infants	35
Intravenous Antibiotic Therapy in Cystic Fibrosis: Home Versus Hospital	44
Listening Partners: Psychosocial Competence and Prevention	170
Mothering in Adolescence: Factors Related to Infant Security	176
Neonatal Outcome and Weight Gain of Black Adolescents	122
Pesticide Exposure and Pregnancy Outcome	22
Pilot Screening for Biotinidase Deficiency in Newborns	126
Prediction of Ourcome of Early Intervention in Failure to Thrive	142
Sickle Cell Anemia: DNA for Newborn Screening Followup	163
SIDS Loss: Psychosocial Impact and Predictors of Coping	91
Standards for the Evaluation of Growth and Nutritonal Status	115
State Census of Technology-Dependent Children	86
Stress, Social Support, and Abuse and Neglect in High-Risk Infants	129
Town Motel Interactions in Lead-Exposed Children	49

